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14. ABSTRACT The <b>overarching goal</b> of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior. This will be accomplished by advancing each of the following strategic areas: 1: Strengthen and support orthopaedic rehabilitation research capabilities through infrastructures and partnerships; 2: Conduct a variety of innovative, high impact, and clinically relevant research studies; 3: Establish a self-sustaining research enterprise by broadening the scope of impact and support for the BADER Consortium. <b>Key Accomplishments to date:</b> Established: Administrative Core, Clinical Research Core and Scientific Technical Cores; approval and establishment of eight clinical research projects; development and implementation of an Omnibus CRADA; established a consortium-wide omnibus PDMS; partnership with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE); developed research focus (gap) areas in partnership with EACE; established and implemented a complete process for the call, submission, review and selection of Consortium funded projects; published the annual BADER call for clinical research proposals, established the BADER Consortium SOPs; completed the hiring of eight research support staff to be placed onsite at MTFs; established partnerships with the VA and NIH; obtained over \$4M of external funding					
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## Introduction

### The BADER Consortium

The **overarching goal** of the BADER Consortium is to Bridge Advanced Developments for Exceptional Rehabilitation. The BADER Consortium is a multi-institutional Consortium that works in concert and partnership with military Medical Treatment Facilities (MTFs), Veteran's Affairs Centers, Academic and Industry leaders to conduct innovative, high-impact, clinically relevant research to further strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.

The success of the Consortium relies on strong partnerships with military Medical Treatment Facilities, the VA and non-government entities in each of the following strategic areas to:

1. Strengthen and support orthopaedic rehabilitation research capabilities:
  - infrastructures and cultures
  - partnerships
2. Conduct a variety of innovative, high impact, and clinically relevant research studies
3. Establish a self-sustaining research enterprise
  - Broaden the scope of impact and support for the BADER Consortium

This report describes how the BADER Consortium has made progress based on the approved Statement of Work for the period September 30, 2016 – September 29, 2017.



## Research accomplishments to date based on Statement of Work

### Administrative Core:

#### **Task 1: Financial Support and Oversight:**

- 1a. Provide oversight of the overall Consortium budget including auditing for allowable expenses, managing re-budget requests and preparing all required financial reports
  - 1b. Ensuring all Military Treatment Facilities (MTFs) receive infrastructure support as required including procurement of materials, personnel, equipment
  - 1c. Manage costs supporting the Cores and Clinical Study Sites
  - 1d. Perform quarterly financial audits for compliance
  - 1e. Maintain files for internal or external audit purposes
- Provided manuscript/publication support costs for BAMC and WRNMMC.
  - Continued to support the procurement of feet/boots for the Schnall study.
  - Quarterly review of the BADER Consortium finances resulted in zero audit findings.
  - Provided financial oversight of the Consortium.
  - Maintained complete and accurate files for internal and external auditing purposes.

#### **Problem areas related to this task:**

- Resources to keep Scientific Technical Cores operational have been depleted.
- Delays in invoicing by subcontractors puts overall award spending behind resulting in excess cash on hand for select BADER funded research projects. Subcontractors are reminded to bill in a timely manner. With all research projects now fully approved and enrolling subjects, we expect to see a significant uptick in expenses.

#### **Task 2: Human Resources Support and Oversight**

- 2a. Manage Human Resources function including recruitment, on-boarding, facility/system access, annual performance appraisals, and handling benefits questions
  - 2b. Provide support as needed for labor relations actions
  - 2c. Manage payroll function for UD employees (at UD and MTF sites)
  - 2d. Work with Steering Committee to develop appropriate job descriptions
  - 2e. Manage recruitment activities of personnel
- Effective September 30, 2017, all CRC staff have transitioned to non-BADER positions.
  - WRNMMC Protocol Coordinator position was vacated effective Jan 6, 2017. We received a request from Dr. Dearth to replace the position. We issued a subcontract to the Henry M Jackson Foundation to fill

the position with a 50% FTE of an existing HMJF contractor to complete the BADER projects at WRNMMC.

- Proposed changes to the Federal Fair Labor Standards Act in the Fall of 2016 affected four BADER staff members. The University opted to follow through on the proposed changes and the four affected staff were notified. This did not change their employment status at the University.
- Status update on all previously hired CRC field staff (N=17):
  - 53% or 9 have transition to MTF positions (3 EACE; 6 other MTF contracts)
  - 23% or 4 have transitioned to civilian clinical research settings
  - 6% or 1 has been accepted to graduate school
  - 12% or 2 have transitioned to a university research office or teaching
  - 6% or 1 has transitioned to a government position (FDA)

**Table 1: Status of BADER funded positions.**

Position	Location	Current Status
Director, Administrative Core	University of Delaware	Filled, part-time
Manager, Clinical Research Core	University of Delaware	Filled, part-time
Administrative Assistant	University of Delaware	Filled, part-time
Consortium Protocol Manager	University of Delaware	Vacant, not filling
Research Associate	WRNMMC	HMJF contractor, part time
Laboratory Engineer	NMCSD	Vacant, not filling
Research Associate	NMCP	Vacant, not filling
Physical Therapy Assistant	BAMC/CFI	Vacant, not filling
Protocol and Data Coordinator	WRNMMC	Vacant, not filling
Protocol and Data Coordinator	NMCSD	Vacant, not filling
Protocol and Data Coordinator	NMCP	Vacant, not filling
Protocol and Data Coordinator	BAMC/CFI	Vacant, not filling
Research Associate	NMCP	Vacant, not filling
Research Physical Therapist	NMCSD	Vacant, not filling
Limited Term Researcher	NMCSD	Vacant, not filling

**Problem areas related to this task:**

- All CRC staff positions in direct support of MTF research expired on September 30, 2017 due to depletion of funds. During this period of performance, news that the proposal to continue BADER efforts was not recommended for funding, we began to lose essential staff early in the period. While select staff have transitioned to EACE positions, others have left to pursue non-MTF opportunities. This

leaves major gaps with these highly trained professionals leaving and does not bode well for the future of MTF orthopaedic rehabilitation research efforts.

**Task 3: Reporting Coordination and Management:**

- 3a. Request, coordinate and submit all required technical reports
- 3b. Preparation of all required financial reports
- 3c. Develop templates for reports to ensure consistency

- Submitted required technical reports.
- Submitted required financial reports.

- **Military Medicine Supplement:** Cecere FA, Stanhope SJ, Kaufman KR, Oldham BW, Shero JC, Mundy JA, guest editors. Raising the Bar: Extremity Trauma Care. *Military Medicine* 2016 Nov;181(S4):1-80.

This publication highlights the three major partnering entities currently supporting orthopaedic rehabilitation research. Today's military health system provides complex extremity trauma care to help injured service members reach their highest level of function. Wounded soldiers have access to technologies and multidisciplinary care that makes it possible for them to reach optimal outcomes. Those advances are possible because of critical synergies that exist between programs that are operating through the Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA). They provide complementary rather than competing care that begins at the point of injury and continues for the rest of a patient's life. The Extremity Trauma and Amputation Center of Excellence (EACE) was created as a joint enterprise between the DoD and the VA to develop a comprehensive strategy to optimize quality of life for service members with traumatic injuries. The Center for Rehabilitation Sciences Research (CRSR) was established to advance the rehabilitative care for service members with combat-related injuries while also educating the next generation of military medicine professionals. The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium was developed to further establish research infrastructures and investigators at DoD and VA sites and to launch a series of multi-team clinical research initiatives. These programs operate independently, but they are designed to be interdisciplinary and collaborative in nature. Together, they provide a unique opportunity to strengthen DoD/VA research programs and influence the long-term direction of care for this unique patient population. It is through this larger coordination, military health professionals will continue to raise the bar in the development and implementation of the new normal for service members with extremity trauma. The cost to the BADER for this second in a series, 80 page, 13 article, Military Medicine Supplement publication was approximately \$32,000.

**Problem areas related to this task:**

- None reported.

**Task 4: General Administrative Support:**

- 4a. Coordinate meetings, calendars, travel, etc.
- 4b. Facilitate communications across Consortium
- 4c. Prepare administrative documents
- 4d. Coordinate all official BADER correspondence

- Dr. Stanhope and Ms. Strickland travelled to Ft. Detrick on October 12, 2016 to provide a status update to Drs. Redington and Green-Parker.
- Submitted a revised request for second no cost extension (NCE) to cover the period 09/30/2017 – 09/29/2019. The second NCE was necessary as all five active BADER funded project PIs requested an additional NCE period to complete their projects.
- Supported travel for Dr. Stergiou to WRNMMC to participate in research collaboration meetings with Dr. Dearth and his team.
- Continued to highlight BADER activities through social media. (Please note: The Communication Specialist position and related activities are supported by F&A dollars, not direct funds)
- Transitioned Jason Wilken’s BADER projects in response to his new position at University of Iowa. Drs. Stanhope and Milbourne participated in multiple teleconferences with EACE regarding the transition.
- Supported BADER Consortium participation in the 2016 AMSUS meeting. The 2016 AMSUS Meeting took place from 29 November – 2 December 2016 at the Gaylord National Resort and Convention Center just minutes from Washington, DC. The theme of the meeting was “Raising the Bar”. The meeting provided a platform for shared accomplishments, research, and strategies for the future of our “new normal” in healthcare as Federal Health Systems take their efforts to the next level of inter-professional collaborative practices. Space was preserved on the program schedule for BADER to provide updates on current projects and continue the visioning for the O&P profession.
- At the AMSUS meeting, the BADER Consortium shared a booth with the Thought Leadership and Innovation Foundation.
- At the AMSUS meeting, the BADER Consortium sponsored – the entire cost and coordination – of the booth occupied by the Extremity Trauma and Amputation Center of Excellence (EACE).
- Provided financial support to WRNMMC for abstract submissions.

**Problem areas related to this task:**

- All strategic operational components of the BADER Consortium have been presented to the MTFs and EACE for transition by the end of BADER funding. These concepts were presented to EACE and MTFs on June 22, 2016 and as of this report, we have not received any official response with regards to transferring BADER infrastructure mechanisms.
- Continuing to support the MTFs at the highest possible level without them feeling abandoned as BADER activities begin to shut down.
- Recent policy changes have made it difficult to travel government employees to scientific meetings.
- The delayed lack of response from USAMRAA regarding our no cost extension request caused angst among staff and PIs.

**Task 5: Policies and Procedures:**

- 5a. Develop, implement and ensure compliance of all SOPs for The BADER Consortium
  - 5b. Ensure compliance with all existing policies and procedures
  - 5c. Create a policy and procedure manual to be distributed to all BADER stakeholders
- This task is complete.

**Problem areas related to this task:**

- No problems reported.

**Task 6: Proposal/Award Coordination and Management:**

- 6a. Management of annual project solicitation process to BADER Affiliates
  - 6b. Management of approved projects (financial, HR, administrative support)
  - 6c. Oversight of all subawards for technical and financial compliance
- Reviewed and approved invoices on subcontracts - subcontractors are reminded to bill on a regular basis. There are still some concerns with the rate of expenditures from subawardees – primarily the research projects.
  - Processed amendments to subawards for no cost extension.
  - Transitioned Jason Wilken’s BADER projects in response to his new position at University of Iowa.

**Problem areas related to this task:**

- BADER projects and support are coming to a conclusion just as the EACE Research Enterprise is getting up to speed. This disconnect will likely be disadvantageous to junior investigators at the MTFs as critical resources that were available through BADER are phased out over the coming months.
- BADER has supported the development of several successful research proposals through staff time, travel support for research collaboration meetings and proposal preparation support. Despite this effort, MTFs are still guarded on providing high-level details (title, agency, investigators) of the proposals so BADER can report the activity. Being able to report this activity would help demonstrate impact of Consortium efforts.
- As part of the sustainability efforts, we attempted to submit a proposal for Jason Wilken as an external PI through the University of Delaware. This concept gained support, however, due to last minute concerns, the proposal was not submitted through UD.
- Delays in approval of Consortium no cost extension put completion of BADER funded studies at risk. All five active projects had requested additional time beyond the current 09/29/2017 end date.
- The reported assignment of investigators Schnall and Pruziner to full time clinical duties appears to have dramatically slowed progress and productivity of their respective BADER funded projects. The apparent change in research support commitment from WRNMMC is considered unfortunate.

**Task 7: Intellectual Property, Material Property, Inventions and Patents Management:**

7a. Management of IP, MP, Invention and Patent agreements

7b. Consult with legal experts as necessary for compliance

- At the request of Drs. Redington and Milutinovich, Ms. Strickland met via phone with Dr. Brian Ilfeld, a recent CDMRP awardee, to discuss the BADER CRADA mechanism. Generic templates were emailed to Dr. Ilfeld and Ms. Strickland offered additional guidance as requested.
- Began process to add Vanderbilt to the BADER CRADA to facilitate work between Vanderbilt and Jason Wilken.
- Completed the process of transitioning Jason Wilken's BADER projects in response to his new position at University of Iowa. This may require additional subcontracts.
- Completed process to add University of Iowa to the BADER CRADA to accommodate Jason Wilken's transition

- Completed amendments to existing CRADAs for the NCE.

Omnibus BADER CRADA: Current status of the CRADA is detailed in Table 2.

Table 2: List of current and pending BADER CRADA partners

<b>Institution</b>	<b>Date of completed agreement</b>
University of Delaware	November 7, 2012
Brooke Army Medical Center	January 3, 2013
C-Motion, Inc	September 20, 2012
Christiana Care Health Systems	October 18, 2012
Mayo Clinic	November 1, 2012
Spaulding Rehabilitation Hospital	October 11, 2012
University of Michigan	Cancelled (Tulsky relocated)
Naval Medical Center San Diego – omnibus CRADA	Rejected
Naval Medical Center Portsmouth – omnibus CRADA	Rejected
Naval Medical Center Portsmouth – Project specific	March 2014
Naval Medical Center San Diego – umbrella Navy CRADA	April 2014
Walter Reed National Military Medical Center	April 2013
Denver Research Institute (DRI) (Grabowski project)	June 2014
Vanderbilt University	Pending
University of Iowa	April 2017

**Problem areas related to this task:**

- No problems reported

**Task 8: Evaluation:**

- 8a. Management of internal evaluation process
- 8b. Primary liaison with external evaluation service (AAAS)

- BADER Administration has presented to the MTF representatives, External Advisory Committee (EAC) and the Grants Officer Representative (GOR) a plan for having the American Association for the

Advancement of Science (AAAS) perform a research evaluation for the BADER Consortium and provide consultation on a sustainment model. At this time, the AAAS evaluation has been placed on hold.

**Problem areas related to this task:**

- No problems reported

**Clinical Research Core (CRC):**

**Task 1: Facilitate approvals of protocols for the use of human subjects in research through local IRBs and through HRPO**

- 1a. Identify DoD requirements for the protections of Human Subjects in Research
  - 1b. Develop materials for and assist PIs in submitting protocols according to the United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) policies and procedures through the ORP for approval
- CRC staff wrapped up their BADER support roles for the approval of human subject protocols.
  - When CRC staff are engaged in human subjects research, protocols are submitted to the UD IRB for acknowledgement. The CRC Manager is provided “view” privileges into the protocol and is copied on emails addressing USAMRMC ORP review/requests of BADER-funded protocols. Currently, a total 10 investigators have shared 24 protocols (8 active; 6 in progress; 10 closed) with the CRC manager. The CRC manager continues to monitor the status of these protocols. This process will continue despite CRC field staff positions expiring on September 30, 2017.
  - During this period of performance, CRC staff continued to manage all protocols at their location **without** the use of the military electronic version of IRBNet.
  - The CRC Manager facilitated several meetings between investigators on the BADER Toolbox study and the USAMRMC HRPO office to coordinate submission activities for the multi-site BADER Toolbox study and to rectify outstanding IRB submissions and previously conflicting messages from HRPO.

**Problem areas related to this task:**

- At times CRC staff receive conflicting information from USAMRMC HRPO as to procedures for submitting documents for multi-site studies. The CRC Manager continuously manages strategies to converge on uniform guidance.



**Task 2: Assist in the development, implementation, and monitoring of standard protocol/human subject research activities that will be instituted across MTFs and Clinical Study Sites throughout the BADER Consortium:**

- 2a. Compile detailed descriptions of all of the planned activities/ interventions/ testing sessions etc. in which subjects will participate in each study and identify existing research resources at MTFs and clinical study sites
  - 2b. Identify and hire Consortium Protocol and Data Coordinators Managers
  - 2c. Identify and hire On-site Protocol Managers and Technicians for MTFs and clinical study sites
  - 2d. Identify data storage needs and work with the Scientific Cores to set up policies and procedures relating to coding of research protocols, subjects and associated data across all MTFs and clinical study sites
  - 2e. Train Consortium Protocol and Data Coordinators in modeling protocols in Data Monitoring System
  - 2f. Implement the Protocol and Data Management System (PDMS)
- The CTDB Operations (Ops) Core continues to engage with BADER investigators regarding the use of the CTDB.
  - This year the Ops Core contributed system improvements on the NICHD protocol and data management system. Particularly:
    - *Data export capabilities* (Form dData dDownload) (FDD) modifications:
      - improved protections so that users at one site cannot see data from another site's users;
      - improved data output via the use of a pipe ( | ) symbol as a data delimiter (in addition to a comma) to allow text responses to contain commas;
      - improved formatting now prints a single data record on a single line, greatly simplifying data analyst's work with preliminary data preparation.
    - *Form templates* – We added a new ability to create a form template permitting data managers to automatically upload external data corresponding to a data entry form, rather than hand-entering each subject's data record one-at-a-time. This new function is particularly useful for legacy data collections and datasets transferred from other databases.
    - *Optimization of text display of CTDB on iPads was completed.*
  - The Ops Core created – for the Toolbox project team - a method for holding virtual “measure consensus meetings.” As a result of this technical support and the use of the virtual meeting software (Adobe Connect and Poll Everywhere), 47 individuals from across the country – including MTF sites - were able to simultaneously participate in the meeting.
  - This year, we continued to hold BADER CTDB Huddle Up sessions on the first Wednesday of each month. Topics during the year included:
    - Introduction to BADER CTDB for new users; 4 people attended.
    - Adding Patients in the CTDB; there were 7 attendees.
    - Quality Assurance and was customized for the research team involved in BADER's Maximizing Outpatient Rehabilitation Effectiveness (MORE) protocol; there were five attendees.

- Additionally, the CTDB Ops Core trained Outcomes Toolbox project staff at partner sites on effective use of Adobe Connect and online-polling/collaboration tool PollEverywhere. Remotely tested A/V setups at participating sites, provided support in PollEverywhere item development, prepared summary reports & graphics. The Ops Core also developed Cognos-based/Excel-extended automated procedure for checking which forms had been administered for each subject at each encounter (interval). Delivered finished product to MORE protocol data supervisor for bi-weekly checking. For the CTDB Portal website the Ops Core updated content and consolidated files stored in other sites.
- Specific to the operation of the CTDB system the Ops Core identified & submitted four items to the NIH in the past three months (resolutions noted, if anything).
  - Upload external file to import data stopped working
  - FDD output file's field order was changed (without notice). New order is QuestionID number (lowest-to-highest). Old sort order matched order of items as they appeared in a form. (Reported 3/10. Added to JIRA as "normal priority".)
  - Unable to delete one locked record in MORE protocol. Nareg removed it noting that the record had been marked as "verified". (3/10)
  - Skip logic that disables normally required question responses is not enforced. (Reported 3/9. Fixed).

**Problem areas related to this task:**

- No problems reported.

**Task 3: Provide training and oversight to On-site Protocol Managers, Technicians and other relevant personnel in study procedures:**

- 3a. Develop and provide training to On-site Protocol Managers and oversee the coordination and maintenance of Institutional Review Board and ORP approvals, including initial review and approval processes, continuing renewal processes, amendment, and addendum and termination approvals.
- 3b. Develop and provide training to On-site Protocol Managers, and oversee procedures to recruit subjects, track accrual, track human subjects compliance, schedule tests, and report adverse events to the ORP and local IRBs.
- 3c. In conjunction with the Scientific Cores, develop and coordinate training for the Consortium Data Coordinators, On-site Research Directors and Technicians and other relevant personnel in data collection and management and quality control procedures

- All CRC field staff maintain CITI certification and site-specific training requirements relevant to study procedures for conducting research with human subjects. Individual CRC staff has completed as available on-site training at their research location.
- This year the CRC staff participated in site-specific conference calls 2x/month with the CRC Manager and in a virtual meeting one-time per month to discuss a variety of topics related to the coordination and conduct of research as their role in the BADER Consortium comes to an end.
- For the purpose of tracking accrual, track human subjects enrollment and study completion status, and report adverse events to the ORP and local IRBs the CTDB Ops Core trained several staff of the multi-site BADER Toolbox study to utilize CTDB.
- To further assist MTF scientists and their collaborators with grantsmanship activities, the CRC staff have determined to established a grant-writing seminar series beginning in January 2017. The seminar series was facilitated by the CRC Manager and focus on grant mechanisms of the most significant funding agencies.

#### **Problem areas related to this task**

- No problems reported.

#### **Task 4: Monitor protocol activities and notify Administrative Core of inadequate study procedures, training or subject recruitment that requires input from the BADER Consortium Coordinating Center**

- 4a. Develop tools for reporting progress in of training activities, subject recruitment and testing, data analysis and quality control measures
  - 4b. Track study progress monthly and notify Administrative Core of underperforming sites and suggest solutions to improve performance
  - 4c. Provide input to Administrative Core for quarterly progress reports of clinical research studies
- CRC staff monitor site-specific protocol activities and coordinate with study PIs to address any inadequacies.
  - In addition to their assignments on BADER-funded research projects, this quarter four CRC field staff provided support for 16 research projects and 7 related activities (see Appendix C). Three CRC staff (Wingate, Hiebert, Hulcher) presented abstracts at the MHSRS conference Aug 2017; Hiebert is co-author on three manuscripts being submitted for publication.
  - As of this report, study enrollments according to data that study teams have entered into the protocol and data management system (CTDB):

- **K2Power:** 1 patient enrolled (no data entered); (no change since last quarter)
- **MORE:** **140** patients established in CTDB (up from **133** last quarter); based on the CTDB enrollment table data: **58** dropped/withdrawn (up from **43**); **46** completed data collection (up from **33**); **29** continued participation; **7** unknown status.
- **ProLegRx:** 21 patients enrolled; 21 completed study (no change since last quarter)
- **Step2Step:** 2 patients enrolled, 1 completed study; 1 no data (no change since last quarter)
- **Walk2Run:** 3 patients enrolled, 1 completed study (2 dropped); (no change since last quarter)
- **Weighted Walking:** no data available in CTDB
- **BADER Toolbox:** **59** patients established in CTDB; **56** completed (up from **31** last quarter); **3** continuing (down from 12 last quarter).
- **PBPT (not BADER funded):** 197 enrolled; it appears that 175 completed the study (85 ROOSEVELT follow-up subjects + 90 TRUMAN follow-up subjects; (no change since last quarter)

#### **Problem areas related to this task**

- No problems reported.

#### **Task 5: Research Development (Dr. Stanhope)**

5a. Identify gap research areas.

5b. Identify and secure sources of external funding.

5c. Connect BCAs with potential collaborators.

5d. Create research pipeline of tech development to basic research to clinical trials.

5e. Support research development at MTFs.

- On September 20, 2017, per the request of Dr. Redington, BADER submitted a follow-on project proposal concept in response to potential funding from Joint Warfare Military Research Program.
- Facilitated the introduction and funded the travel for Dr. Stergiou of to visit WRNMMC to discuss and establish a research collaboration with Dr. Dearth. <http://www.unomaha.edu/college-of-education/biomechanics-core-facility/about-us/directory/nicholas-stergiou.php>
- Facilitated the development of the RAPIDFAB study team and subsequent proposal led by Dr. Wilken with members from the Center for Composite Materials, the Department of Kinesiology and Applied Physiology at the University of Delaware.
- Continued to Mentor Mr. John Collins - stationed at the NMCSD – on the development of a generalized method for quantifying the sources and flow of mechanical work during the “push off” phase in normal, impaired and amputee walking.

- Dr. Stanhope established a collaboration with Dr. Wilken at the Center for the Intrepid and Dr. Goldberg at Hofstra University on the development of a novel clinical tool to visualize joint and segmental work.
- Dr. Stanhope directed a collaborative effort with his UD (Ebrahimi), C-motion, Inc. (Kepple) and NMCSO (Collins) to develop and test a groundbreaking method for eliminating the age-old segmental power and rate-of-energy imbalance using a novel 6 DOF segmental power analysis.
- Dr. Stanhope travelled to Hanover, NH to participate in the TREAT (Fostering Advances in Rehabilitation and Assistive Technology) scientific advisory board meeting and to promote technology translation through MTF and VA sites. <http://treatcenter.org/>
- Dr. Stanhope consulted with the CEO of BionX, Charles S. Carignan, MD, (<http://www.bionxmed.com/>) to discuss the difficulties BionX has encountered with attempting to include MTF sites in multi-site clinical trials of their emPOWER ankle device and other devices in the development pipeline. The emPOWER ankle is being tested by Dr. Pruziner in her BADER funded study. A proposal to study the BionX powered AFO was submitted to the 2016 CDMRP OORP grant opportunity. However, it is our understanding that no MTF site was included in the proposal.
- Coordinating BADER related activities at the upcoming MHSRS meeting.
- Facilitated the transition of Wilken studies and activities and led coordination with EACE and MTF sites.

**Problem areas related to this task:**

- No problems reported.

**Task 6: Development and Coordination of the Call for Proposals (Dr. Davis)**

- BADER completed Task 6 in Year 3. BADER has eight approved protocols completed or ongoing, meeting the original goal of funding 6-8 projects.

**Problem areas related to this task:**

- No problems reported.

## Scientific Technical Cores:

### **Biomechanics Core (BC): C-Motion, Inc.**

*Funding for the Biomechanics Core ended September 29, 2016. See prior reports for complete details of work completed.*

### **Rehabilitation Outcomes Measurement (ROM) Core: University of Delaware**

#### **Task 1: Establish outcomes library and training libraries, develop infrastructure for working with investigators.**

- 1a. Submit relevant IRB related documents as necessary.
- 1b. Conduct literature reviews to identify relevant outcomes measurement tools related to orthopedic injuries.
- 1c. Build measurement library for utilization of relevant outcomes measures for research studies.
- 1d. Provide workshops, web-ex presentations, and seminars to train BADER personnel about Patient Reported Outcome (PRO) measures.
- 1e/f. Prepare training materials for data collection of patient reported outcomes. Prepare measurement platform for BADER proposals (develop Assessment Center or alternative method for data capture).

1a. All sites have valid IRB-approved protocols. We have contacted sites and updated our records.

1b. We have conducted and finished our systematic review of 32 measures of physical functioning that have established use in orthopedic/amputation research in amputee populations and have documented the relevant research on the psychometric properties and construct validity. Extensions of this work continue as part of BADER Toolbox and the scope of this effort has continued to expand as a result of feedback from the BADER investigator team. Completion of the expanded work is expected in October 2017.

1c. These literature searches and reviews have facilitated establishment of a measurement library for BADER-relevant outcomes measures. The library has been updated with recent publications. We have provided information to the BADER Clinical Trials Data Base team to see how this work could be integrated with the Clinical Trials Database. We have obtained permissions for 22 of the measures to be included thus far.

1d-e. We developed and delivered training materials so that Toolbox investigators could utilize PROMIS from Assessment Center. See Appendix E, F, G.

1f. We have, on a customized basis, built Assessment Center data collection platforms for the MORE study and the K2 Power BIOM study. We have subsequently facilitated subject PINs for data collection and follow-up PIN requests as well.

**Problem areas related to this task:**

- No problems reported.

**Task 2: Evaluate relevant outcomes measurement instruments and ensure relevance for use in BADER studies. Ensure that floor and ceiling is appropriate for the population. Develop new item content as appropriate.**

- 2a. Develop focus group guides to identify measurement issues.
- 2b. Prepare and execute focus group meetings at collaborating DoD sites (months 2-3)
- 2c. Transcribe focus group guides and prepare NVivo (qualitative software) coding guides (months 4-6)
- 2d. Code and reconcile focus group data (months 7-9)
- 2e. Develop new item content to increase measurement sensitivity/specificity of orthopedic injuries (months 10-12).

Additional focus group data collection was completed at Walter Reed and CFI, to supplement data collected from focus groups conducted at San Diego, Walter Reed, and CFI/BAMC.

These five additional focus groups were transcribed, coded and reconciled, and qualitative analyses and reports and were updated. As a result of this additional data collection, we reached content saturation. This supplemental qualitative data collection has been incorporated to provide an updated and comprehensive analysis, which has been summarized and shared with co-investigators. Several hundred new items have been drafted in item pools and were further edited and prepared for expert review and subsequently need to go through this stage and a cognitive interviewing process, which will be conducted as part of a DoD BAA-funded grant. We are also working to develop a system through REDCap for managing item content efficiently throughout the item life cycle. This work has begun and is being implemented for the BAA project.

**Problem areas related to this task:**

- No problems reported.

**Task 3: Consult and review study proposals for the BADER Consortium**

- 3a: Submit relevant IRB related documents as necessary.
- 3b: Work directly with prospective PIs of BADER projects. Provide consultation on outcomes measurement design issues and integration into proposals and research methodology.
- 3c: Review proposal ideas and provide feedback on outcomes design.
- 3d: Work with investigators to provide design measurement platforms and train research personnel.
- 3e: Develop new measurement techniques tailored for specific interventions as appropriate.

- We have worked closely with Dr. Scott Tintle, an orthopedic hand surgeon at WRNMMC, who was interested in submitting a DoD grant, in collaboration with Dr. Dearth, focused on developing outcomes measures for those who have received hand transplants. We worked closely and extensively with Drs. Tintle and Dearth to provide training, input, feedback, and support on measurement approaches and practices, which ultimately led to the co-development of a Reconstructive Transplant Research grant proposal submitted in December 2016 (ultimately not funded). We have initiated another set of proposal planning meetings with Drs. Tintle and Dearth to submit a new transplant outcomes proposal in fall 2017.
- We have provided proposal review and support to Dr. Wilken and to Dr. Dearth for subsequent planned grant submissions. We are awaiting feedback from these investigators to see if we should continue these efforts.
- ROM Core staff conducted another set of meetings with investigators at WRNMMC, CFI and NMCSD in spring 2017 to provide research and measurement support for their and our joint efforts.
- 3a, b & c. We continued to discuss new research with other members of the BADER consortium. We met with Dr. Jason Wilken and team to discuss research agendas and to build the data collection platform for the MORE proposal. We met with Drs. Chris Dearth and Alison Pruziner to consult on the BIOS proposal and to review and discuss research agendas. We have met with Marilyn Wyatt at Naval Medical Center San Diego to discuss their research agenda and identify areas in which we can continue to provide support and leverage BADER activities.
- The ROM Core also conducted another set of meetings with investigators at WRNMMC, CFI and NMCSD in spring 2017 to provide research and measurement support for their and our joint efforts.

**Problem areas related to this task:**

- No problems reported.

**Biostatistics Core: Christiana Care Health Systems (CCHS)**

The Biostatistics Core for the BADER Consortium is a fee for service model that provides services when requested. Due to changes in personnel at Christiana Care Health Systems, the Biostatistics Core will utilize resources available at the University of Delaware under the same fee for service model.

**Task 1: Participate in development of project specific aims and research design with investigators.**

- No updates for this task.



**Task 2: Develop statistical analysis plans (SAP) for each research project.**

- No updates for this task.

**Task 3: Assist in the design of datasets for analysis. Provide transfer capabilities and expertise.**

- No updates for this task.

**Task 4: Conduct statistical analyses.**

- The MORE study continues data collection. Interim statistical analysis will be conducted within 3 months or less to assess data quality and completeness. Final statistical analyses will be conducted after complete data collection.

**Task 5: Provide assistance in developing presentations, writing reports and manuscripts.**

- No updates for this task.

## **Progress Reports on Clinical Studies**

(please see Appendix D for updated Quad Charts)

	<b>2012.1 – Step2Step (CLOSED)</b>	<b>2012.2 – RETRAIN (CLOSED)</b>	<b>2013.1 – ProLeg Rx</b>	<b>2013.2 – K2Power</b>	<b>2013.3 – Outcomes Toolbox</b>	<b>2014.1 MORE</b>	<b>2014.2 Backpack</b>	<b>2014.3 Trauma Outcomes</b>
<b>Proposal submitted</b>	Oct 2010	Oct 2010	Dec 2012	Dec 2012	Dec 2012	Nov 2013	Nov 2013	Dec 2012
<b>Scientific Review</b>	May 2011	May 2011	December 2012	December 2012	December 2012	December 2013	December 2013	Dec 2012
<b>GSC approval</b>	June 2012	April 2012	March 18, 2013	March 18, 2013	March 18, 2013	February 28, 2014	February 28, 2014	Mar 2013
<b>Contract negotiation docs sent to CDMRP</b>	June 2012	July 2011	August 2013	August 2013	December 2014	December 2014	December 2014	Jan 2015
<b>CDMRP approval</b>	August 2012	August 2012	February 2014	February 2014	February 2015	February 2015	February 2015	August 2012
<b>Omnibus CRADA executed</b>	December 2012	October 2012	March 2014	March 2015	February 2015	April 2015	April 2015	February 2015
<b>BADER PI agreement signed</b>	August 2012	October 2012	April 2013	Pending	Pending	April 2014	March 2014	October 2014
<b>IRB approvals</b>	August 2012	June 2013	Oct 2013	May 2014	May 2015	June 2015	June 2015	*
<b>HRPO approval</b>	September 2012 (aim 1) April 12, 2013 (aim 2)	June/July 2013	COMIRB approval Oct 2013	June 2014	Feb 2016	June 2015	June 2015	*
<b>Subject pool</b>	*	*	45	14	149	200+	23	*
<b>Subjects screened</b>	46	12	32	12	149	154	19	*
<b>Subjects enrolled</b>	46 (Aim 1: 22, Aim 2: 1, Aim 3: 23)	2	22	9	149	154 (136 patients, 18 therapists)	16	56 patients, 34 providers
<b>Subjects Completed</b>	46	0	22	0	149	0	16	*
<b>Presentations</b>	23	5	17	3	4	0	5	*
<b>Publications</b>	4 (3 more in revision)	0	4	0	2	0	1 in progress	*

**“Improving Step-To-Step Control of Walking in Traumatic Amputees”**  
***“STEP2STEP”***

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** Gait and balance training are essential for patients with lower limb amputation because of their high fall risk. However, little scientific evidence exists to guide efforts to develop such training programs. The purpose of this study is two-fold: to determine how step-to-step control strategies differ between patients with varying levels of amputation and to determine how these patients respond to a virtual reality based training intervention. Addressing these two issues will provide an essential foundation from which we can design more effective training protocols. Enhanced training will take place in a fully immersive virtual reality (VR) environment so we can apply well controlled and ecologically relevant motions to the walking surface. Effective VR-based gait training programs may provide significant advantages over traditional gait training, putting therapists in control of the training environment and allowing them to quantitatively monitor patient progress in real time. We expect this will yield significant generalization to real world walking. We will conduct a single-center study including 30 patients with varying degrees of lower limb amputation to determine the relative effects of VR based treatment on walking step-to-step control strategies. We will test each subject before, during, and after training as well as at an approximate 2-week follow-up while walking both in the VR environment and while walking over flat and uneven ground. Step-to-step control measures will then be compared across the group of patients using regression analyses against clinical performance measures to better understand the effects of physical ability on step-to-step control. Additional intra-subject analyses will be conducted to look at changes in walking over the course of the intervention.

Title:	2012.1: “Improving Step-To-Step Control of Walking in Traumatic Amputees”	
Funded Amount:		
Principal Investigators:	Jonathan Dingwell, PhD	Department of Kinesiology & Health Education, University of Texas at Austin, Austin, TX
	Jason Wilken, PhD	Military Performance Lab, Center for the Intrepid, Department of Orthopaedics & Rehabilitation, Brooke Army Medical Center, San Antonio, TX
Collaborators:	Joseph P. Cusumano, Ph.D.	Pennsylvania State University, Department of Engineering Science & Mechanics
Accruals	Aim #1: 21 total subjects (9 patients + 13 controls) Aim #2: 1 subject Rehab Frogger Study: 23 total subjects (10 patients + 13 controls)	

IRB Approvals:	Our IRB application for Specific Aim #1 was determined to qualify for “ <i>exempt</i> ” status so therefore no annual renewals are required. Our IRB application for Specific Aim #2 has been approved by BAMC IRB and has received HRPO approval. Approval expires: January 9, 2017
Amendments to IRB	None reported.
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	None reported.
Finances:	Awarded a no cost extension through September 2016 Award amount: Spent to date: % spent to date: 99.7% % award period complete: 100%

**“Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”**

**“RETRAIN”**

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** Lower extremity amputations significantly impact a soldier’s gait function and their ability to return to active duty. Despite standard rehabilitative care that includes gait training, loading remains elevated in the intact extremity, increasing the risk for the development of degenerative joint disease. *The purpose of this study is to examine whether symmetry of loading can be improved in both walking and running using real-time feedback in individuals with unilateral, transtibial amputations.*

Title:	2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”	
STATUS:	<b>Project ended 09/30/2015</b>	
Funded Amount:		
Principal Investigators:	Irene Davis, PhD, PT	Spaulding Rehabilitation Hospital
	Alison (Linberg) Pruziner, DPT, ATC	Walter Reed National Military Medical Center
Collaborators:	Steve Jamison, PhD Matthew Ruder, MS Devjani Saha, PhD	Elizabeth Nottingham Elizabeth Husson Amanda Wingate, BA
Accruals:	<b>SNRC:</b> Potential subjects contacted: 23 Potential subjects screened (phone): 15 Lab screened: 6 (5 did not qualify) Subjects enrolled: 1	<b>WRNMMC:</b> Potential subjects contacted: 10 Potential subjects screened: 6 Subjects enrolled: 1 Subject withdrawals: 1
Adverse events:	None reported.	
Serious adverse events:	None reported.	
Finances:	Award amount: Spent to date: % spent to date: 87% Project dates: 10/01/2012 – 09/30/2015 Dr. Davis was granted a no cost extension to 09/30/2015. % complete: 100%	

**2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma**

***"Trauma Outcomes"***

Title:	2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma	
Funded Amount:	Funded through Research Outcomes Measurement Core budget	
Principal Investigator:	David Tulskey, PhD	University of Delaware
Collaborators:	Christopher Dearth, PhD	WRNMMC
	Marilynn Wyatt, MPT	NMCSD
	Jason Wilken, PhD	BAMC/CFI
IRB Approvals:	NMCSD IRB approval received (August 21, 2013). HRPO Approval received March 2014. HRPO Log Number A-17117.5	

**Details of this project can be found under Research Outcomes Measurement Core Statement of Work, Task 2**

**Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?**

***“The ProLegRx Study”***

**Abstract:** There are currently no science-based, objective methods for optimizing running-specific prosthesis (RSP) prescription. Existing practices can waste time, money, and resources and do not necessarily provide the best prosthetic prescription. Due to the severity of impairment caused by a leg amputation and the healthcare costs sustained over the lifetime of a person with an amputation, it is extremely important to improve RSP prescription so that Soldiers and Veterans with amputations can regain the greatest possible level of functional ability and return to active duty, if they choose. Our goal is to develop tools for clinicians to prescribe running-specific leg prostheses that facilitate optimal function for Soldiers and Veterans with transtibial amputations. We intend to systematically vary the stiffness and height of distance-running RSPs and measure the biomechanical and metabolic effects of running at the speed required for a subject’s age/sex 50<sup>th</sup> percentile Physical Fitness Test (PFT) 2 mile run and at one standardized speed, 3 m/sec. We also intend to systematically vary the stiffness and height of sprint-running RSPs and measure the biomechanical and performance effects of running across a range of speeds. Then, we will combine results from distance-running and sprint-running prostheses to develop clinically relevant, quantitative algorithms for prosthetic stiffness and height prescription based on a subject’s weight, amputation level, limb segment lengths, and desired running speed. The results of our research will be disseminated to clinicians and will improve RSP prescription for people with leg amputations. We hope to improve and expedite rehabilitation for Soldiers and Veterans with transtibial amputations and to save time, money, and resources. Optimizing RSP prescription would facilitate aerobic conditioning, reduce injury risk, improve running economy (the metabolic demand at a given running speed) and improve performance; thus improving the quality of life and reducing the healthcare needs of Soldiers and Veterans with leg amputations.

Title:	2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?	
Funded Amount:		
Principal Investigator:	Alena Grabowski, PhD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
Collaborators:	Rodger Kram, PhD	Dept. of Integrative Physiology, University of Colorado
	Ryan Stephenson, MD	Dept. of Veterans Affairs Eastern Colorado Healthcare System
	Michael Litavish, CP	Dept. of Veterans Affairs Eastern Colorado Healthcare System
Accruals:	Potential subjects contacted: 45 Potential subjects screened: 32 Subjects enrolled: 22 Subjects completed: 22	
IRB Approvals:	COMIRB: Expires August 21, 2018	



Amendments to IRB:	We expanded the age range of participants to include people between 18-55 years old.
Adverse events:	None
Serious adverse events:	None
Problems or barriers to research:	None reported
Finances:	Award amount: Spent to date: % spent to date: 93% Project dates: 10/01/2013 – 12/31/2017 % complete: 95%

### **Research Progress Update:**

**Specific Aim 1:** Quantify the biomechanics, metabolic demands, and socket pistoning of subjects with transtibial amputations using distance-running running-specific prostheses (RSPs) of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with distance-running RSPs.

**Specific Aim 2:** Quantify the biomechanics, performance, and socket pistoning of subjects with transtibial amputations using sprint-running RSPs of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with sprint-running RSPs.

**Specific Aim 3:** Develop a clinically relevant, quantitative algorithm for RSP stiffness and height prescription based on a subject's weight, level of amputation, limb segment lengths, and desired running speed.

#### ***SA 1 and 2, Task 1:***

- (a) We obtained IRB approval from the Colorado Multiple Institutional Board Review (COMIRB) for the human experimental studies in Specific Aims 1 and 2. The University of Colorado Boulder IRB ceded to COMIRB. We have obtained review and approval of approved IRB documents by the USAMRMC Office of Research Protections (ORP).

#### ***SA 1 and 2, Task 2:***

- (a) Otto Bock, Ossur, and Freedom Innovations have provided over 60 prostheses to accommodate our subjects. We used a mechanical testing machine (MTS) within the Department of Mechanical Engineering at the University of Colorado Boulder to quantify the stiffness of each running-specific prosthesis (RSP).
- (b) We quantified the stiffness of each prosthesis and will compile the results of the stiffness tests into a technical report that we intend to publish.
- (c) We needed to build a test jig and determine the angle to test each prosthesis.

- (d) We built a test jig, measured stiffness at different angles and have established a prosthetic testing protocol. We have analyzed the results and our manuscript has been published in Plos One: ON Beck, P Taboga, & **AM Grabowski**. Characterizing the mechanical properties of running-specific lower-limb prostheses. *PLoS ONE* 11(12): e0168298. doi:10.1371/journal.pone.0168298, 2016.

**SA 1 and 2, Task 3:**

- (a) For the running protocol, we have recruited 15 participants and 15 have completed the study. For the sprinting protocol, we have recruited 15 participants and 15 have completed the study.
- (b) We will continue to network with the community to disseminate our results and promote future research. We were invited to attend the USOC Paralympic Track and Field research clinic in Chula Vista, CA, and have attended the Hanger Running Clinic in Golden, CO, and the 5480 Challenge Paralympic Track and Field meet in Cherry Creek, CO. We organized a research team meeting that included: the prosthetist that is building the sockets, the prosthetist that is fitting and aligning participants, and a prosthetist from the USOC.
- (c) Because each athlete with an amputation has a different build height, we have recruited participants in a specific order.
- (d) We have obtained measurements from all athletes with leg amputations and recruited athletes with the tallest build height first and then with shorter build heights so that we re-used each RSP.

**SA 1, Task 4:**

- (a) A certified prosthetist from our research team has fit and aligned subjects to each distance-running RSP brand during an accommodation session. Subjects then ran on a treadmill to accommodate to each of these distance-running RSPs. The height of each RSP was adjusted for each subject prior to the experiment so that they could use each RSP brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects came into the lab for three experimental data collection sessions. During these experimental sessions, we measured their biomechanics, metabolic demands, and socket pistoning while they ran with different stiffness and height distance-running RSPs on an instrumented treadmill.
- (b) We have recruited all subjects and they have completed the protocol.
- (c) We calculated the average required speed for the Physical Fitness Test (PFT) 2 mile run for all participants and found that it is nearly the same as our standardized speed of 3.0 m/s.
- (d) We reduced the number of running trials so that athletes will only run at 3 m/s with all of the different prosthetic configurations.

**SA 2, Task 6:**

- (a) A certified prosthetist from our research team has fit and aligned subjects to each sprint-running RSP brand during an accommodation session. Subjects then ran on a treadmill to accommodate to each of these sprint-running RSPs. The height of each RSP was adjusted for each subject prior to the experiment so that they could use each RSP brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects came into the lab for six experimental data collection sessions. During these experimental sessions, we measured their biomechanics, top speeds, and socket pistoning while they ran with different stiffness and height sprint-running RSPs on an instrumented treadmill.
- (b) We have recruited all the subjects that can complete the protocol.
- (c) One of our subjects had bilateral leg amputations and bilateral arm amputations, which presented a challenge for dismounting the treadmill at top speed.

- (d) We built custom hand-rails that allowed this participant to achieve his top speed and dismount the treadmill safely.

**SA 1, Task 5:**

- (a) Analyze the data from Task 4 to determine the optimal stiffness and height of a distance-running RSP for each individual. Prepare a manuscript and publish the results of our study in a peer-reviewed scientific journal.
- (b) We submitted four abstracts in 2015 that were accepted by the American Society of Biomechanics (ASB) and the Rocky Mountain ASB (RMASB) meetings, submitted two abstracts in 2016 that were accepted by the ASB and American Orthotic and Prosthetic Association (AOPA), and submitted two abstracts in 2017 that were accepted by the ACSM and ASB.
- (c) Our abstracts were accepted and presented as talks and/or posters for each meeting. We have two manuscripts that were submitted to peer-reviewed journals.
- (d) Mr. Beck presented at the 2015 RMASB, 2015 ASB, 2016 ASB, 2016 AOPA, 2017 RMASB, and 2017 ACSM meetings. We have published two manuscripts: ON Beck, P Taboga, & **AM Grabowski**. Prosthetic model, but not stiffness or height, affects the metabolic cost of running for athletes with unilateral transtibial amputations. Published March 30, 2017. *Journal of Applied Physiology*  
<http://jap.physiology.org/content/early/2017/03/28/japplphysiol.00896.2016>  
ON Beck, P Taboga, & **AM Grabowski**. Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. Published Jan. 19, 2017. *Journal of Applied Physiology*  
DOI: 10.1152/japplphysiol.00587.2016

**SA 2, Task 7:**

- (a) Analyze the data from Task 6 to determine the optimal stiffness and height of a sprint-running RSP for each individual. Prepare manuscripts and publish the results of our study in peer-reviewed scientific journals.
- (b) We submitted four abstracts to the 2015 American Society of Biomechanics (ASB) and the Rocky Mountain ASB meetings, two abstracts to the 2017 ASB and RMASB meetings, and one abstract for the 2017 MHSRS meeting.
- (c) Our abstracts were accepted and presented for each meeting.  
Dr. Taboga presented two posters at the 2015 RMASB and ASB meetings, and one poster at the 2017 ASB meeting. Mr. Beck had podium presentations at the 2017 RMASB and ASB meetings. Dr. Grabowski presented a poster at the 2017 MHSRS meeting. We have published one manuscript: ON Beck, P Taboga, & **AM Grabowski**. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? 14: 20170230. Published 28 June 2017. *Royal Society Interface*  
DOI: 10.1098/rsif.2017.0230 and we have one manuscript under review: ON Beck & **AM Grabowski**. Case studies in physiology: The biomechanics of the fastest sprinter with a unilateral amputation. *Journal of Applied Physiology*. We are in the process of writing 3-4 manuscripts that will be submitted to peer-reviewed journals regarding the effects of prosthetic stiffness and height on top speed and across speeds.

**SA 3, Task 8:**

- (a) Combine the results from Specific Aims 1 and 2 to create a comprehensive, user-friendly algorithm for prosthetists and clinicians to use so that they can make optimal RSP prescriptions. Prepare a manuscript and publish our algorithm in a free public access peer-reviewed journal. Distribute our algorithm to clinicians through VA education programs and conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress. Distribute our height-adjustment bracket to clinicians through VA education programs and

conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress.

- (b) We have compiled our results and will begin to work on a document that summarizes our optimal prescription algorithm.
- (c) We are in the process of preparing a manuscript and document that will be submitted to a peer-reviewed journal, prosthetists and manufacturers.
- (d) We had a conference call with Ossur to discuss a revision of their recommended stiffness categories for distance running. We presented our results to VA prosthetists at the Denver Jewell Amputation Clinic in January 2017. Dr. Grabowski has presented the results of the research thus far to the NCAA Track and Field Rules Committee to support the participation of an athlete with bilateral transtibial amputations in the 2017 track season.

### **Preliminary results:**

**Table 1.** Manufacturer-recommended average RSP stiffness across models (Össur Flex-Run (FR), Freedom Innovations Catapult FX6, Ottobock 1E90 Sprinter, Össur Cheetah Xtend) based on running 3 and 6 m/s. Stiffness includes the rubber sole that comes with each model, except for the Xtend, which includes the Flex-Run's sole. The 1E90 Sprinter had the lower stiffness value for a given user mass and manufacturer-recommendation across models.

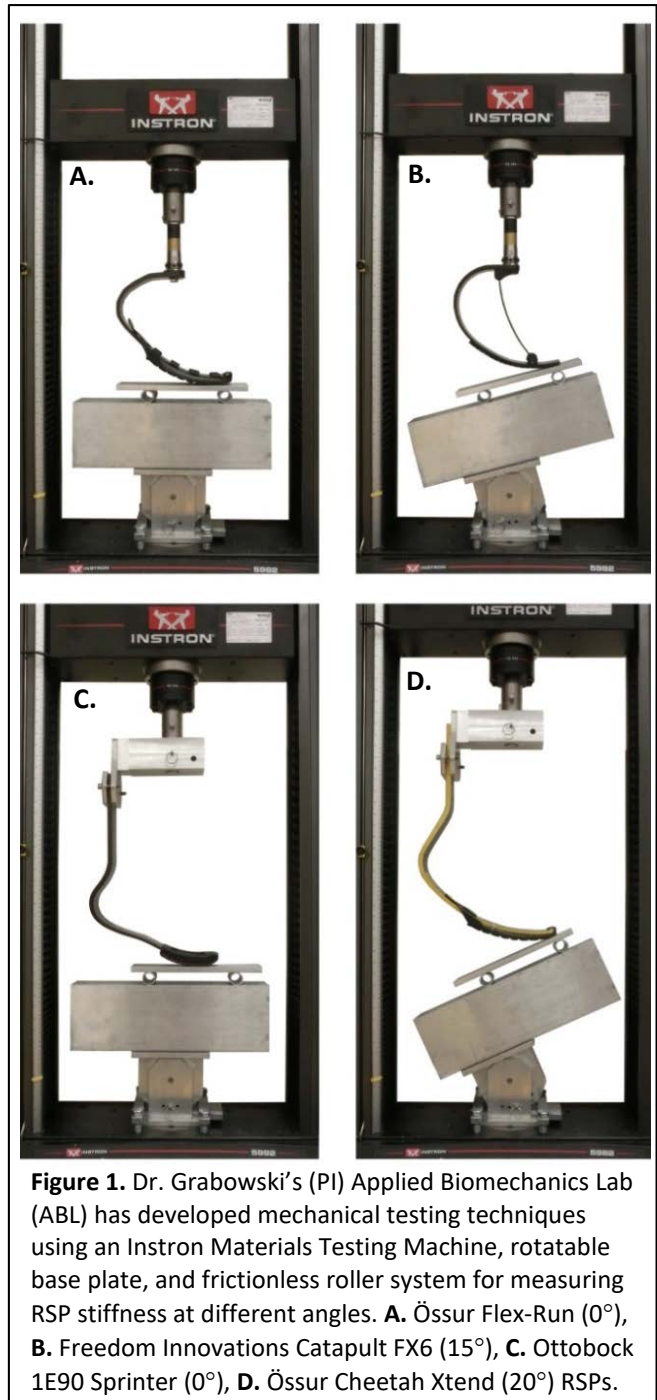
Mass (kg)	3 m/s				6 m/s			
	FR (kN/m)	Catapult (kN/m)	Sprinter (kN/m)	Xtend (kN/m)	FR (kN/m)	Catapult (kN/m)	Sprinter (kN/m)	Xtend (kN/m)
55	18.0	17.4	16.2	20.7	20.4	20.4	19.0	21.5
60	20.6	20.1	18.6	23.2	22.6	25.8	19.5	23.5
65	22.1	20.8	19.1	23.7	23.7	27.6	22.7	23.9
70	22.9	22.8	21.8	26.1	26.1	29.9	23.1	26.4
75	23.7	23.5	22.2	26.6	27.7	30.7	23.5	26.8
80	26.2	25.9	22.7	28.8	29.2	33.7	26.4	28.9
85	26.1	26.5	23.2	29.3	31.3	34.5	26.8	29.4
90	29.5	29.9	25.9	32.3	33.4	41.2	27.2	32.4
95	31.4	30.5	26.3	32.7	34.7	42.0	27.6	32.8
100	31.8	31.1	26.7	33.2	35.3	42.8	32.1	33.1

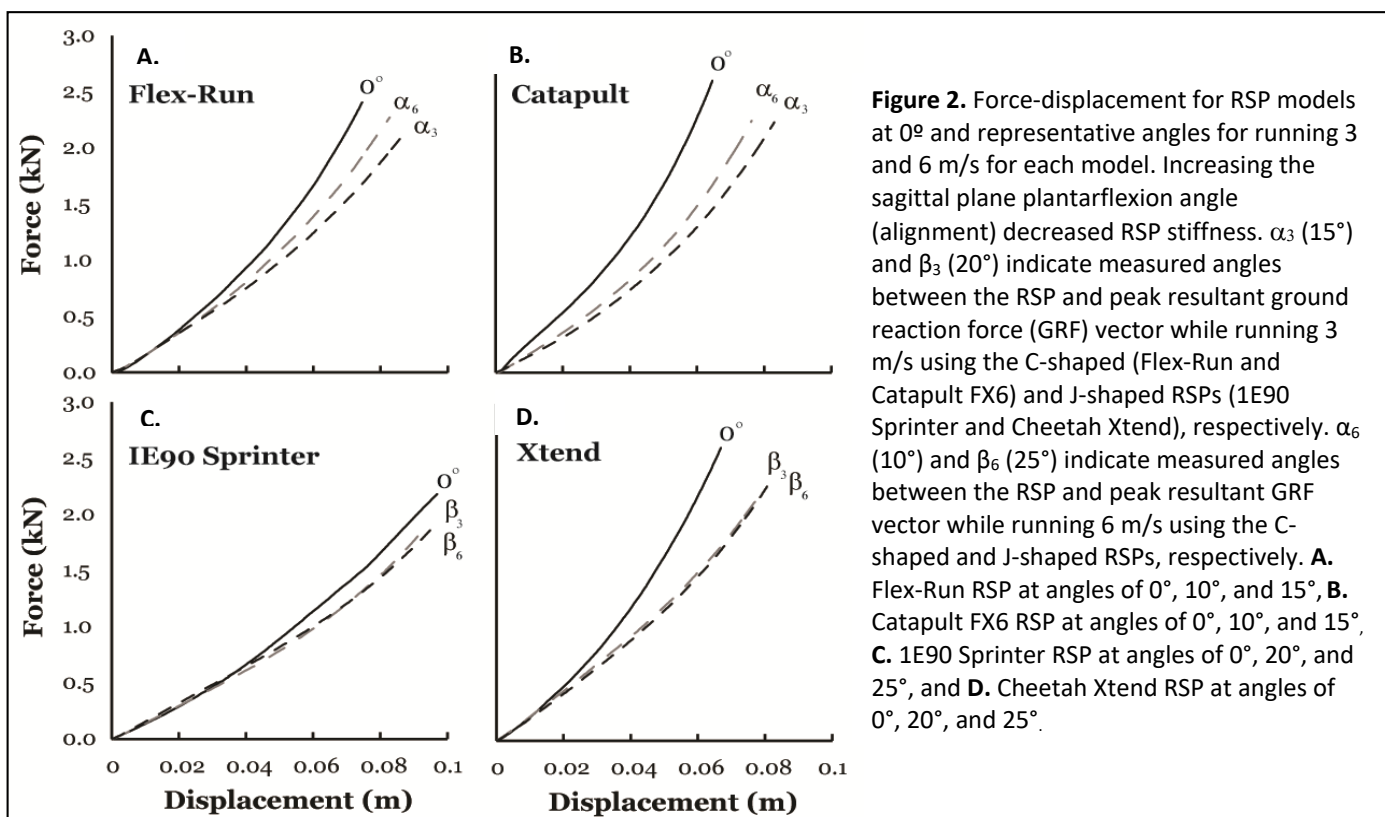
We are currently completing a series of studies to assess the effects of using different running-specific prosthetic (RSP) model, stiffness, and height on the biomechanics, metabolic costs, and top speeds of 30 athletes with transtibial amputations. First, we established the mechanical stiffness values (in kN/m) of different stiffness categories of four models of RSPs (Beck et al., 2016). Prior to our study, the actual mechanical stiffness values of RSPs (i.e. kN/m) were unknown. The mechanical stiffness of RSPs likely affects the performance of athletes with transtibial amputations; however, each prosthetic manufacturer recommends RSPs based on arbitrary and subjective stiffness categories rather than performance-based metrics. Thus, we characterized the stiffness of 55 RSPs using an Instron materials testing machine across different stiffness categories, heights, and models (two

from Össur, one from OttoBock, and one from Freedom Innovations) using forces and sagittal plane angles representative of those measured from previous studies of 11 athletes with transtibial amputations during running (Fig. 1). We found that the actual stiffness values of manufacturer-recommended stiffness categories varied between prosthetic models (Table 1) ( $p < 0.001$ ) and that characterizing prosthetic force-displacement profiles with a second degree polynomial explained 4.4% more of the variance than a linear function (Fig. 2) ( $p < 0.001$ ); suggesting that RSP stiffness is not linear. Also, prosthetic stiffness was 10-39% less at the sagittal plane angles typical of running 3 m/s and 6 m/s (10-25°) compared to vertical (0°) (Figs. 1, 2) ( $p < 0.001$ ), and stiffness was inversely related to prosthetic height in J-shaped ( $p < 0.001$ ), but not C-shaped prostheses. From our RSP stiffness results, we recommend that RSPs should be tested under the demands of the athlete's respective activity to derive relevant characterizations of stiffness and function and that stiffness values should be reported.

After characterizing the mechanical stiffness of RSPs, we analyzed the biomechanical and metabolic effects of using these RSPs during running and sprinting for 30 athletes with transtibial amputations. Each athlete used three RSP models (Össur, Freedom Innovations, and OttoBock) with three stiffness categories per model (manufacturer recommended, and  $\pm 1$  stiffness category) at three different heights (prosthetist recommended, and  $\pm 2$  cm), a total of 15 different prosthetic configurations (Beck et al. 2017). We determined the optimal prosthetic configuration for running as the RSP that minimized the net metabolic cost of transport (CoT), which is the metabolic demand per unit distance minus the cost of standing. We determined the optimal prosthetic configuration for sprinting as the RSP that maximized top speed, which is the fastest attainable speed that an athlete can maintain for 8-10 strides without moving back on the treadmill. We then analyzed the performance of ten athletes with unilateral and five athletes with bilateral transtibial amputations for running and of ten athletes with unilateral and five athletes with bilateral transtibial amputations for sprinting.

Runners with a unilateral transtibial amputation minimized their metabolic cost during running by using the least stiff J-shaped OttoBock 1E90 Sprinter RSP (Fig. 3A), which elicited 5.2 and 4.2% lower net CoT compared to the C-shaped Freedom Innovations Catapult FX6 and Össur Flex-Run RSPs, respectively ( $p < 0.01$  model effect). The





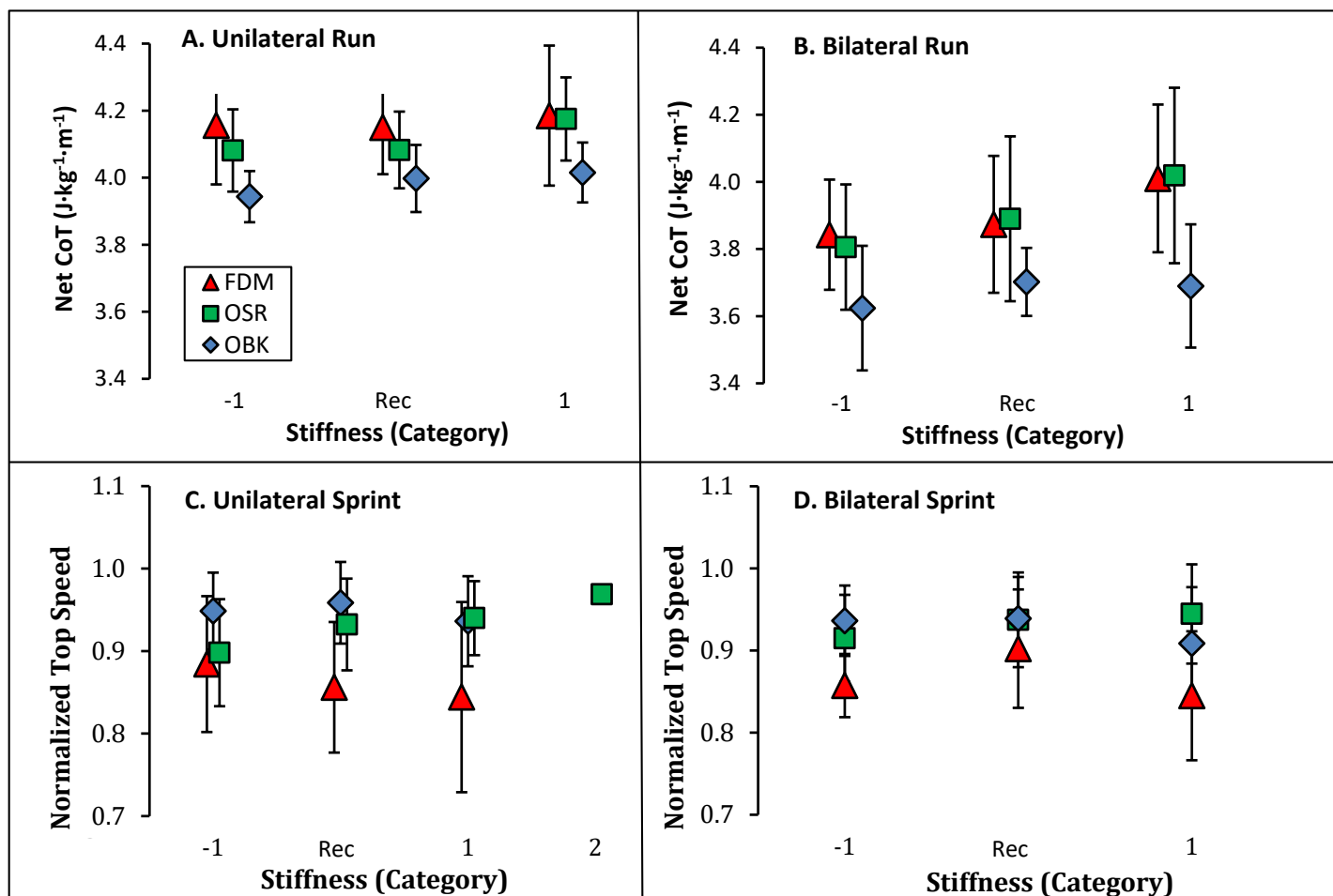
**Figure 2.** Force-displacement for RSP models at 0° and representative angles for running 3 and 6 m/s for each model. Increasing the sagittal plane plantarflexion angle (alignment) decreased RSP stiffness.  $\alpha_3$  (15°) and  $\beta_3$  (20°) indicate measured angles between the RSP and peak resultant ground reaction force (GRF) vector while running 3 m/s using the C-shaped (Flex-Run and Catapult FX6) and J-shaped RSPs (1E90 Sprinter and Cheetah Xtend), respectively.  $\alpha_6$  (10°) and  $\beta_6$  (25°) indicate measured angles between the RSP and peak resultant GRF vector while running 6 m/s using the C-shaped and J-shaped RSPs, respectively. **A.** Flex-Run RSP at angles of 0°, 10°, and 15°, **B.** Catapult FX6 RSP at angles of 0°, 10°, and 15°, **C.** 1E90 Sprinter RSP at angles of 0°, 20°, and 25°, and **D.** Cheetah Xtend RSP at angles of 0°, 20°, and 25°.

optimal RSP configuration reduced peak vertical ground reaction force asymmetry between affected and unaffected legs (Beck et al. 2017). Runners with bilateral transtibial amputations also minimized their metabolic cost during running by using the least stiff J-shaped Ottobock 1E90 Sprinter RSPs (Fig. 3B), which elicited 5.3 and 2.7% lower net CoT than the C-shaped Freedom Innovations Catapult FX6 and Össur Flex-Run RSPs, respectively ( $p < 0.001$  model and stiffness effect). For this group, a one category reduction in RSP stiffness, which corresponds to a ~4 kN/m reduction in actual stiffness, improved net CoT 3.7% ( $p < 0.001$ ). Interestingly, we found that there was no effect of RSP height on net CoT in runners with unilateral or bilateral transtibial amputations (Beck et al. 2017).

Sprinters with a unilateral transtibial amputation achieved 7.1% and 9.8% faster top speeds ( $p < 0.001$ ) by using the J-shaped Össur Cheetah Xtend and Ottobock 1E90 Sprinter RSPs compared to the C-shaped Freedom Innovations Catapult FX6 RSP (Fig. 3C), and did so by increasing peak vertical ground reaction force and decreasing leg stiffness. Sprinters with bilateral amputations also achieved faster top speeds by using J-shaped Össur Cheetah Xtend and Ottobock 1E90 Sprinter RSPs, which increased top speed by 7.1% and 6.9% ( $p < 0.001$ ) compared to the C-shaped Freedom Innovations Catapult FX6 RSPs (Fig. 3D). These sprinters improved top speed by decreasing ground contact time and increasing peak vertical ground reaction force. Interestingly, we found no effect of RSP height on top speed in sprinters with unilateral or bilateral transtibial amputations.

In general, the results of our studies show that the stiffness of an RSP, which depends on the sagittal plane alignment, can affect metabolic costs and biomechanics and use of J-shaped RSPs improves performance compared to use of C-shaped RSPs. The reduced metabolic costs and improved top speeds with the use of J-shaped compared to C-shaped RSPs may have been due to sagittal plane alignment and/or increased prosthetic mechanical energy return (less hysteresis). The sagittal plane alignment of the J-shaped RSPs may have yielded resultant GRFs that were better aligned with the leg joints, thus mitigating the muscular force required to counteract the ground reaction force-joint moment to support bodyweight. J-shaped RSPs recycle a greater

percentage of the stored elastic energy during recoil compared to the C-shaped RSPs. It is possible that the enhanced mechanical energy return from J-shaped RSPs in combination with better sagittal plane alignment mitigated the muscular work input needed to sustain running, enabling more economical force production. It is plausible that because RSP stiffness decreases with a more plantarflexed alignment (Table 1, Fig. 2) and we have found that the least stiff RSPs improve performance (Fig. 3), a more plantarflexed alignment within a given RSP stiffness category would further improve biomechanics, metabolic costs, performance, and satisfaction in people with unilateral and bilateral transtibial amputations.



**Figure 3.** Average ( $\pm$ SEM) net metabolic cost of transport (CoT) for **A.** 10 runners with unilateral transtibial amputation and **B.** 5 runners with bilateral transtibial amputations using three RSP models with the manufacturer-recommended (Rec) stiffness category and  $\pm 1$  category at recommended height. Average ( $\pm$ SEM) normalized top speeds for **C.** 10 sprinters with unilateral transtibial amputation, **D.** 5 sprinters with bilateral transtibial amputations using three RSP models with the manufacturer-recommended (Rec) stiffness category and  $\pm 1$  or  $+2$  category at recommended height. FDM are Freedom Innovations Catapult FX6, OSR are Össur Flex-Run for distance running and Össur Cheetah Xtend for sprinting, and OBK are the Ottobock 1E90 Sprinter RSPs. The lowest net CoT, which optimized performance, occurred when **A.** runners with unilateral amputation used the OBK RSP at one category lower than Rec, and **B.** runners with bilateral amputations used the OBK RSPs at one category lower than Rec. The fastest top speed, which optimized performance, occurred when **C.** sprinters with unilateral amputation used the OBK or OSR J-shaped RSP and **B.** sprinters with bilateral amputations used the OBK or OSR J-shaped RSPs. There was no effect of stiffness category on top speed.

**Pending Support based on BADER funded work:**

CDMRP PRORP W81XWH-17-PRORP-CTRA (Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount: \$

**Project Title:** Optimizing the Alignment and Performance of Running-Specific Leg Prostheses

**Short project description:** We propose to quantitatively study the effects of different running-specific prosthetic sagittal plane alignments on running and sprinting performance in Veterans and service members with transtibial amputations and integrate these findings into clinical best practices for optimal prosthetic prescription.

CDMRP PRORP W81XWH-17-PRORP-CTRA (Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Does Use of a Powered Ankle-Foot Prosthesis Improve Physical Activity?

**Short project description:** We intend to compare the physical activity duration and intensity of Service members and Veterans with a transtibial amputation using a passive-elastic and the BiOM prosthesis to a non-amputee cohort.

CDMRP PRORP W81XWH-17-PRORP-ATA (Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Optimizing prosthetic prescription for running in Service members with transfemoral amputations

**Short project description:** The overall goal of this project is to develop objective guidelines for prescribing running-specific prostheses to Service members, Veterans, and civilians with transfemoral amputations.

CDMRP ORORP W81XWH-16-OPORP-PORA (Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Optimizing the Alignment and Performance of Running-Specific Leg Prostheses

**Short project description:** We propose to quantitatively study the effects of different running-specific prosthetic sagittal plane alignments on running and sprinting performance in Veterans and service members with transtibial amputations and integrate these findings into clinical best practices for optimal prosthetic prescription.

CDMRP DHA-17-CRII-MWHRA (Wyatt)

01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation

**Short project description:** The goals of this project are to determine how the stiffness and weight of an orthosis (IDEO) or running-specific prosthesis effect the running performance and preference of female Service members with limb salvage or leg amputations.

**Submitted but Unfunded Support:**

VA Merit Review “Optimizing Leg Prosthetic Stiffness for Level, Uphill, and Downhill Running” Grabowski PI (Not Awarded)

CDMRP Orthotics and Prosthetics Outcomes Research Program “Optimizing Running-Specific Leg Prosthetic Stiffness for Uphill & Downhill Running” Grabowski PI (Not Awarded)

BADER Consortium Project Proposal CDMRP PRORP “Effects of leg prosthetic stiffness on uphill & downhill running” Grabowski PI (Not awarded)



BADER Consortium Project Proposal CDMRP PRORP “Overcoming obstacles with a trans-tibial amputation”  
Grabowski PI (Not awarded)

BADER Consortium Project Proposal CDMRP PRORP “Optimizing trans-femoral prosthetic prescription for running performance” Grabowski PI (Not awarded)

BADER Consortium Project Proposal CDMRP PRORP “The effects of running-specific leg prosthetic alignment on running and sprinting performance” Grabowski PI (Not awarded)

#### **Publications in Refereed Journals (BADER-related only):**

ON Beck, P Taboga, & AM Grabowski. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? 14: 20170230. Published 28 June 2017. Royal Society Interface DOI: 10.1098/rsif.2017.0230

ON Beck, P Taboga, & AM Grabowski. Prosthetic model, but not stiffness or height, affects the metabolic cost of running for athletes with unilateral transtibial amputations. Published March 30, 2017. Journal of Applied Physiology <http://jap.physiology.org/content/early/2017/03/28/jap.physiol.00896.2016>

ON Beck, P Taboga, & AM Grabowski. Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. Published Jan. 19, 2017. Journal of Applied Physiology DOI: 10.1152/jap.physiol.00587.2016

ON Beck, P Taboga, & AM Grabowski. Characterizing the mechanical properties of running-specific lower-limb prostheses. *PLoS ONE* 11(12): e0168298. doi:10.1371/journal.pone.0168298, 2016.

#### **Invited Talks - Grabowski**

***European College of Sport Science congress 2018.*** Invited to speak (1 of 3 speakers) for a symposium, “Do prosthetic legs enhance or hinder running performance?” Dublin, Ireland.

***International Conference on Intelligent Robots and Systems*** Invited to speak (1 of 8 speakers) for a symposium, “On the Energy Economy of Robotic and Biological Systems” The biomechanical and metabolic effects of using of powered and compliant leg prostheses on performance during human locomotion. Vancouver, British Columbia, Canada.

***American Orthotic & Prosthetic Association 2017.*** Invited to speak (1 of 8 speakers) for a symposium, “Power in Prosthetics” Las Vegas, NV.

***NCAA Track and Field Rules Committee 2017.*** The effects of using running-specific leg prostheses on the performance of athletes with transtibial amputations. Indianapolis, IN.

***Human Movement Variability Conference 2017.*** Effects of Leg Prostheses on Running, Sprinting, and Jumping Omaha, NE.

***CU Athletics Department Sports Governance Center 2017.*** Does the use of a leg prosthesis provide an advantage or disadvantage to Paralympic athletes? Boulder, CO.

***Boulder Valley School District Arapahoe Campus 2017.*** Do leg prostheses provide an advantage or disadvantage for running, sprinting, & jumping? Boulder, CO.

***American Academy of Orthotists and Prosthetists Annual Meeting 2017.*** How do leg prostheses effect the running, sprinting & long jump performance of Paralympic athletes? Chicago, IL.

***USOC Paralympic Ambulatory Sprints and Jumps Coaches Summit 2017.*** Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? Colorado Springs, CO.

**Department of Veterans Affairs Eastern Colorado Healthcare System Jewell Clinic Amputee Team Meeting 2017.** The effects of leg prostheses during walking, running, and sprinting. Denver, CO.

**CU Athletics Department Sports Governance Center 2016.** Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? Boulder, CO.

**University of Colorado Boulder Integrative Physiology Department Colloquium 2016.** Effects of leg prostheses on walking, running, sprinting, & jumping. Boulder, CO.

**Keynote at CU Boulder Research Administrators Breakfast 2016.** Do leg prostheses augment walking, running, sprinting or jumping? Boulder, CO.

**International Press Conference - Markus Rehm about to jump to Rio 2016.** Biomechanical comparison of the long jump of athletes with and without a below the knee amputation. Cologne, Germany. 1 of 3 researchers and the only US researcher invited to contribute.

**Northern Arizona University Biology Department Seminar 2016.** Can leg prostheses augment walking & running performance? [https://twitter.com/cbi\\_nau/status/702989123976495106](https://twitter.com/cbi_nau/status/702989123976495106) Flagstaff, AZ.

**International Research Forum on Biomechanics of Running-Specific Prostheses 2016.** Effects of running-specific leg prostheses on performance. Tokyo, Japan. 1 of 3 researchers invited from the US.

**Naval Medical Center San Diego 2015.** Can leg prostheses restore function during running and/or sprinting? San Diego, CA

**University of Colorado Boulder Integrative Physiology Department Colloquium 2015.** The effects of using leg prostheses during walking & running – Can we augment performance? Boulder, CO.

**American Society of Biomechanics Symposium 2015.** Wearable active and passive leg prostheses; Can we augment performance in people with an amputation? Columbus, OH.

### **Conference Presentations**

ON Beck, P Taboga, & AM Grabowski. *American Society of Biomechanics* 2017. Boulder, CO. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

P Taboga, ON Beck, & AM Grabowski. *American Society of Biomechanics* 2017. Boulder, CO. Top sprinting speed is influenced by prosthetic model, but not stiffness or height, for athletes with bilateral transtibial amputations.

ON Beck & AM Grabowski. *2017 Military Health System Research Symposium*. Kissimmee, FL. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

ON Beck, P Taboga, & AM Grabowski. *Rocky Mountain American Society of Biomechanics* 2017. Estes Park, CO. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

ON Beck & AM Grabowski. *American College of Sports Medicine* 2017. Denver, CO. Is the metabolic cost of running different for athletes with unilateral versus bilateral transtibial amputations?

KZ Takahashi, SJ Stanhope, & AM Grabowski. *International Research Forum on Biomechanics of Running-Specific Prostheses* 2017. Tokyo, Japan. Locomotion on springs: from biological limbs to prosthetic devices

ON Beck & AM Grabowski. *American Orthotic & Prosthetic Association* 2016. Boston, MA. Characterizing the Stiffness of Running-Specific Prostheses.

ON Beck, P Taboga & AM Grabowski. *American Society of Biomechanics* 2016. Raleigh, NC. Characterizing the Stiffness of Lower-Limb Running-Specific Prostheses.

KZ Takahashi, K Sharp, P Taboga, M Wyatt, & AM Grabowski. *International Research Forum on Biomechanics of Running-Specific Prostheses* 2016. Tokyo, Japan. Energy storage and return of running specific prostheses.

ON Beck, P Taboga & AM Grabowski. *American Society of Biomechanics 2015*. Columbus, OH. Asymmetric forces increase the metabolic cost of running for unilateral amputees.

ON Beck, P Taboga & AM Grabowski. *American Society of Biomechanics 2015*. Columbus, OH. Lower prosthetic stiffness minimizes the metabolic cost of running for individuals with bilateral leg amputations.

P Taboga, ON Beck & AM Grabowski. *American Society of Biomechanics 2015*. Columbus, OH. Optimal running prostheses for sprinters with bilateral leg amputations.

P Taboga, ON Beck & AM Grabowski. *American Society of Biomechanics 2015*. Columbus, OH. Optimal running prostheses for sprinters with unilateral leg amputations.

ON Beck, P Taboga, & AM Grabowski. *Rocky Mountain American Society of Biomechanics 2015*. Estes Park, CO. Lower prosthetic stiffness minimizes the metabolic cost of running for individuals with bilateral leg amputations.

ON Beck, P Taboga, & AM Grabowski. *Rocky Mountain American Society of Biomechanics 2015*. Estes Park, CO. Asymmetric forces increase the metabolic cost of running for individuals with a unilateral leg amputation.

P Taboga, ON Beck, & AM Grabowski. *Rocky Mountain American Society of Biomechanics 2015*. Estes Park, CO. Optimal running prostheses for sprinters with unilateral leg amputations.

P Taboga, ON Beck, & AM Grabowski. *Rocky Mountain American Society of Biomechanics 2015*. Estes Park, CO. Optimal running prostheses for sprinters with bilateral leg amputations.

**“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators”**

***“The K2POWER study”***

**Abstract:** Advances in lower limb prostheses have allowed for improvements in function and participation in activities for individuals with transtibial limb loss. Advancements in passive ankle prostheses are still limited in their ability to assist with forward progression and push-off because of their inability to produce positive network. Recent advancements to powered prostheses have proposed the potential to provide positive network, returning these individuals to a level of function and efficiency similar to those without limb loss. The objectives of this proposal are to identify differences in gait, efficiency, function, and quality of life between using a standard passive prosthesis versus a powered ankle prosthesis, and to see if changes remain stable for up to six months after the initial fitting. We wish to address these objectives in individuals with lower limb loss that are not capable of fully interacting in their environment and community. This proposed project will assist with prosthetic prescription decisions regarding individuals with transtibial limb loss with varying levels of function, as advanced technology is often not directed at the more disabled population, despite these individuals potentially having the most to gain from this technology.

Twenty individuals with transtibial limb loss will be recruited to participate in this longitudinal study: ten who function at a Medicare Functional Classification Level (MFCL) K2-level and ten who function at a MCFL K3-level. Participants will be evaluated in their current passive ankle prosthesis, be fit with a powered ankle prosthesis, and be followed during six visits over six months. Testing during these six months will include analyzing how the participants walk, how much energy they are using to walk, their balance and endurance, and subjective reports of how they feel and what they are able to do in the prosthesis. We expect results will show differences in walking measures that indicate a change in risk of secondary injury to the intact limb, such as osteoarthritis; will identify changes in efficiency with walking and in balance and endurance; and will measure the users satisfaction with the device and how the user is able to interact with his/her home and community lives, to indicate differences in ability to re-integrate into these roles.

Results from this proposal will have a short-term impact of helping drive prosthetic prescription of powered ankle prostheses for individuals with transtibial limb loss who are K2 and K3-level walkers. The long-term impact of results from this proposal will be the potential for increasing opportunities for lower level walkers to have access to advancements in technology, especially as these technologies expand to include more joints, such as the knee and hip. This proposal will be able to demonstrate the ability of a lower level walker to control and respond to a powered prosthetic device. Additionally, this proposal will allow us to determine if power makes any positive changes to the user’s walking, efficiency, balance, endurance, and ability to engage in their daily activities at home and within their community, and if any changes are sustainable.

Title:	2013.2: “Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators”	
Funded Amount:		
Principal Investigator:	Alison A. Pruziner, DPT	Walter Reed National Military Medical Center

Collaborators:	Caitlin Mahon, MS	Walter Reed National Military Medical Center
	Joseph B. Webster, MD	Hunter Holmes McGuire VA Medical Center
	Bradford Hendershot, PhD	Walter Reed National Military Medical Center
	David S. Tulskey, PhD	University of Delaware
IRB Approvals:	Expires May 6, 2018	
Amendments:	One amendment submitted to recruit participants with limb loss due to vascular causes but who are currently in a recovered/remission state in their disease.	
Adverse events:	None reported	
Serious adverse events:	None reported	
Problems or barriers to research:	None reported	
Recruitment:	Total number of subjects contacted: 14 Total number of potential subjects screened: 12 Total number of subjects enrolled: 9	
Finances:	Award amount: Spent to date: % spent to date: 51% Project dates: 03/01/2014 – 09/29/2019 % complete: 67%	

### **Research Progress Update:**

For each aim, describe: (a) what you have done, (b) what the next steps will be, (c) the administrative and scientific challenges you have experienced and (d) what you are doing to overcome them.

- a) Aim 1: During this quarter, one participant initiated data collection, completed data collection in his passive foot and has been fit with his powered prosthetic foot.  
Aim 2: During this quarter, one subject completed data collection, three previously enrolled subjects continued their data collections (three data collection sessions), and one participant withdrew from data collection due to the time and travel commitments.  
Both Aims: During this quarter, an interim data analysis was also initiated to develop an abstract for submission to the American Academy of Prosthetics and Orthotics. Further discussed below, efforts have been initiated this quarter to add the Richmond VA as a recruitment and data collection site.
- b) Aim 1: During the upcoming quarter, we will continue post (power) collections for the newly enrolled participant, and recruitment efforts will continue through the Department of Rehabilitation at WRNMMC to help us meet our recruitment goals.  
Aim 2: During the upcoming quarter, collection will continue for the participants listed above (five additional follow-up collections scheduled).  
This quarter will also be spent completing regulatory requirements to add the Richmond VA as a recruitment and data collection site, and completing investigator training to ensure seamless data collection once approval has been obtained. We will be bringing a new team member onboard to assist

with these efforts, and this quarter will be ensuring this team member becomes fully trained to independently conduct data collection sessions. Finally, we will finalize the interim analysis to submit an abstract to the American Academy of Prosthetics and Orthotics.

- c) Recent changes in local recruitment regulation has limited our recruitment opportunities to only DoD health care beneficiaries. Therefore, efforts have been initiated to add the Richmond VA as a recruitment and data collection site. At this time, there are no plans to continue civilian recruitment.
- d) Formally expand recruitment and collection to the Richmond VA by adding them as a site.

**Preliminary results:**

No new data to be presented at this time, but interim analysis in process and data will be provided in next quarter report.

**Study completion projection:** September 29, 2019

**Presentations (BADER-related only):**

Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 19 February 2014

Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 20 February 2015

Wingate AF, Kisala PA, Pruziner AL, Dearth CL, Tulsy DS. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. *Military Health System Research Symposium*. 17-20 August 2015, Ft. Lauderdale, FL

**“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma”**  
***“QOL Toolbox”***

**Abstract:** As a result of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND), an unprecedented number of wounded warriors have had combat-related major traumatic limb injuries that include amputation of one or more limbs. These wounded warriors are typically treated for long periods of time at Military Treatment Facilities (MTF) within the Department of Defense (DoD) and later, upon discharge from active duty, at Department of Veterans Affairs Medical Centers (VA) or civilian hospitals. Unfortunately, the health care that is provided across the DoD MTF sites and the VAs is not well coordinated. Individual clinicians and researchers use a wide variety of measurement tools to assess their patients and the lack of standardization across sites makes it difficult to track progress or compare functioning and outcomes across the major treatment facilities. This often results in a lack of coordination of medical care. From a research perspective, the lack of uniformity in measurement tools makes it difficult to compare patients across studies or follow individuals over time as they are transferred to and receive care from different medical facilities. This hinders our ability to study these injured service persons over time to better understand their course of recovery and identify the most effective types of treatments. Because upper limb injury was a rare occurrence prior to OEF/OIF/OND there have been few studies on this patient group and little evidence to inform the design of optimal clinical care guidelines.

People who have had upper extremity amputation of one or both hands and/or arms, major traumatic damage to their limbs without amputation, or who have had multi-limb amputations are understudied groups. When research is performed, the medical community has focused on assessment of patient physical functioning (e.g., limitations in an individual’s strength and their ability to walk and stand) and placed less emphasis on measuring the injured individual’s ability to return back to a healthy and productive life by participating in society, and resuming work and social relationships (known as community reintegration). Entire areas of functioning revolving around social participation have been largely ignored in clinical practice. Moreover, without coordination between the MTFs, the VAs, and civilian hospitals, researchers and clinicians at the different sites will use different measures, making it very difficult to accumulate data across sites. A coordinated approach to assessment for this population would help improve clinical care and allow research at different sites to be aggregated. This grant hopes to improve all of these things.

A central aim of this grant is to develop a “toolbox” of outcome assessments that is comprehensive and includes measures of community integration and quality of life, as well as assessments of physical activity and limitations in body functions. The proposed study is unique because it brings together a large group of clinicians and researchers from the major military treatment facilities that treat individuals with traumatic amputation (i.e., the Center for the Intrepid/San Antonio Military Medical Center, Naval Medical Center in San Diego, Walter Reed National Military Medical Center) and one of the largest VA hospitals and amputation centers (Tampa VA) and one of the oldest and largest civilian hospitals (Rusk Rehabilitation at New York University) along with leaders in measurement from the University of Michigan and Providence VA. This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma, clinicians, policy makers, and research

investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales that can help bring standards and uniformity to the field.

Given the dearth of research on individuals with upper extremity amputation, we plan to validate the toolbox by administering the upper extremity toolbox measures to individuals who have had upper limb amputation at 3 MTFs, a VA, and a civilian hospital. The instrument will be reassessed to help us ascertain reliability and other psychometric properties. Through this collective work we will introduce a new level of cooperation and uniformity to the field. We will study individuals with upper extremity amputations, a subgroup of injured service people who have been underrepresented in research in the past. We will also emphasize the vital areas of community reintegration and quality of life assessment with MTF and VA clinical practice to improve the lives of individuals who have had these traumatic limb injuries. These efforts will ultimately result in improvements to clinical practice which will directly benefit persons with both combat and non-combat related limb trauma and amputation.

Title:	2013.3: “Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma”	
Funded Amount:		
Principal Investigator:	David Tulsy, PhD	University of Delaware
Collaborators:	Alison Pruziner, DPT; Christopher Dearth, PhD	WRNMMC
	Jill Cancio, PhD	BAMC/CFI
	Marilynn Wyatt, MPT	NMCSD
	Hilary Bertisch, PhD	NYU Langone Medical Center
	Linda Resnik, PT, PhD	Providence VA Medical Center
	Gayle Latlief, DO	James A. Haley Veteran’s Hospital, Tampa FL
	Claire Kalpakjian, PhD	University of Michigan

Number of subjects enrolled	Focus groups: 56 patients, 34 providers  Toolbox administration: 59 participants (12 lower extremity, 47 upper extremity)
IRB Approvals	Expires: November 25, 2017

The Toolbox project was approved later than anticipated (May, 2015) and, hence, work began much later than planned and steady progress has been made to “catch up” and ensure that all deliverables will be accomplished by March 2018 (given the BADER no-cost extension). From May-December, 2015 (when scientific staff was hired), we were very active initiating start-up activities. This included:



1. Establishment of subcontracts with Tampa VA, Henry H. Jackson Foundation, Geneva Foundation, Oceanside, University of Michigan, and New York University.
2. Recruitment and hiring of scientific personnel at University of Delaware who have extensive experience in outcomes research, including: Jerry Slotkin, Ph.D., Matt Cohen, Ph.D., Deborah Micklos, MA, James Holdnack, PhD, Callie Tyner, PhD, Keith Bredemeier, PhD, and Aaron Boulton, PhD. The experience and high caliber of the team greatly enhances our ability to meet project deliverables.
3. Additionally, 6 scientists were trained to serve as “focus group moderators” to allow for rapid collection of data and streamline the timeline. The moderators included: David Victorson, Ph.D., David Tulsy, Ph.D., Matt Cohen, Ph.D., Hilary Bertisch, Ph.D., Carly Maletich, MA, and Pamela Kisala, MA.
4. Recruitment and hiring of senior administrative support was conducted. Vanessa Foreman started as a senior business administrator on December 1, 2015 and has been in charge of facilitating Toolbox subcontracts, subcontractor payments, and budget management for the project. She works closely with other recently hired personnel. Vanessa left the University in October 2017. Rachel Strickland from BADER/UD will support Toolbox activities until a replacement is hired.
5. We have met in person multiple times with Alison Pruziner and Chris Dearth at WRNMMC, Jason Wilken and Jill Cancio at Center for the Intrepid, Marilyn Wyatt at the NMCS D and Gail Latlief at the Tampa VA to discuss revised timelines and project goals.

Most of the research activities have been accomplished. The research activities to date include:

1. An initial set of focus groups was successfully completed at WRNMMC, Center for the Intrepid, and NMCS D. In addition, focus groups were completed in early 2016 at the Tampa VA, and follow-up focus groups were held at CFI and WRNMMC, to ensure adequate sample size for our research, and based on recommendations from the investigator team (see Appendix E for more details).
2. Qualitative analyses have been conducted on these data. Several steps were undertaken to accomplish our goals. These include:
  - a. Transcription of focus group meetings
  - b. “Chunking” of focus group transcripts
  - c. Creation of a codebook
  - d. Codebook review by project co-investigators
  - e. Identification, hiring, and training of coders
  - f. Achievement of inter-rater reliability target
  - g. Completion of coding process
  - h. Data analyses and preparation of tables and a formal presentation of results
  - i. An “executive summary” of the process and results

3. A state-of-the-art systematic literature review has made substantial progress and nears completion.
  - a. A review of 36 measures (94 distinct scales) and 156 articles on community reintegration has been completed. Furthermore, a manuscript to disseminate this work has been prepared and published.
  - b. A review of 55 measures and 260 articles for upper extremity has been completed. A manuscript describing this work has been completed and published.
  - c. A review of 16 measures and 69 articles for lower extremity performance measures has been completed to date. A draft methodology has been written and article reviews continue.
  - d. Finally, a review of 16 measures and 73 articles on quality of life has been completed to date. Additional search terms have been added and significant additional work has been recommended to ensure thoroughness.
  - e. Given the increased scope of work in identifying additional articles and measures, and the amount of time needed to review, the timeline has been updated for completion. It will be completed by October 2017, with draft articles targeted for February 2018.
  
4. Two in-person investigator meetings have been held on November 18-19 in Chicago and April 27-29 in Bethesda with all key BADER Toolbox Co-Investigators and stakeholders. These have been highly successful in providing opportunities for co-investigators – including those at MTFs and VA sites – to see the scientific progress that had been made on the focus groups/qualitative analyses and literature reviews, and to begin more fully planning for the stakeholder consensus meeting, subsequent data collection, and other project deliverables.

With an emphasis on thoroughness, quality, and timeliness, we have moved effort and work into the next grant year and based upon discussions with the investigative team, several decisions were made that impact the scope of work of this project. This work is being accomplished with no or minimal impact on the total budget of the project. However, funds and timing of tasks have necessarily been shifted to the final year (2016-2017), with some funds and activities carried over into the granted no-cost extension year (2017-18). Among the decisions/recommendations made by the team at these meetings were the following (outcomes/updates follow each in parentheses):

- a. There were concerns that “saturation of issues” had not been achieved with the focus group data we had already obtained in 2015. Therefore, it was decided to conduct additional focus groups for upper extremity and limb salvage to ensure saturation. (These new focus group meetings were held at Center for the Intrepid, Walter Reed, and Tampa VA. This required extensive increase in personnel time and the result was that all the qualitative analytic steps needed to be repeated and new analyses had to be conducted and results prepared.)
  
- b. The co-investigators thought that while the literature reviews were extensive, there were several types of orthopedic injuries that should have been included. Hence, they argued

that, for thoroughness, the search teams should be expanded to include several new type of injuries. This caused the scope of the literature review to triple and required significant increase in personnel time and delayed the timeline. As a result, the timelines for completing the quality of life and lower extremity reviews were moved to winter 2017. (To produce state-of-the-art reviews, the expanded reviews are in process despite the increased cost, and are expected to be completed by the end of October.)

- c. To engage as many stakeholders as possible, the group strongly suggested targeting presentations at key conferences including the FFAST meeting in Long Beach, CA and the MHSRS meeting in Florida in August. Additionally, a presentation was set up at the EACE quarterly meeting to provide an update and seek opportunities for collaboration. Proposals for presentation were submitted and we were selected to present at the MHSRS meeting. Drs. Tulsky, Cohen and Slotkin attended the 2016 presentation in Orlando, FL, which met with positive feedback from attending stakeholders and discussion of potential new work opportunities. Dr. Tulsky also attended and presented at an EACE quarterly meeting in San Antonio on May 17, 2016. A proposal for presentation at the 2017 MHSRS meeting was also been submitted and accepted for poster presentation, and was presented August 29, 2017. Such activities were not planned in the original project but thought to be very important by the group.
- d. Reorganize and expand the consensus meeting process to two separate meetings, separating upper extremity from lower extremity meetings. The overwhelming feedback from the team was that it would be much more productive and efficient and more inclusive of military expertise and leadership to hold two separate “consensus” meetings to review and agree upon measures to be included in the BADER Toolbox – one focused on upper extremities and the other focused on lower extremity functioning, with both including related quality of life and reintegration measures. It was strongly felt that many of the experts for upper vs. lower would be different, and the best recommendations and decisions could be made by ensuring the right people are included in each meeting, and that many fewer experts may attend a single meeting. It was suggested that an “upper” meeting be held in the early fall and a “lower” meeting be held in early winter. The impact of this decision was to increase the travel costs and effort to conduct this work. An upper limb consensus meeting was indeed held on September 26, 2016 and appears to have been highly successful. More on this is described under #5 below. A second meeting was held on February 7, 2017, and was also successful.
- e. Create a corresponding split in training and initiation of the data collection for the BADER Toolbox pilot, such that collection of upper would begin in the late fall and continue through spring (to allow more time to identify and collect data on participants, which comprise 80% of the proposed sample), and lower data collection would commence in spring and would require only 2-3 months to complete the smaller number of cases. This was deemed much more effective and efficient in targeting the appropriate measures to the appropriate group

of participants and to ensure the project is completed by September 2017 as planned. This approach also necessitates two training sessions with personnel at data collection sites, different, targeted training materials (including videos), etc. (Due to further changes in timelines and regulatory submission requirements, the data collection efforts have been rejoined, and there was one combined upper and lower data collection period, which was completed in September 2017 across four data collection sites.)

- f. Take opportunities to present/disseminate information to stakeholder groups to increase knowledge of the Toolbox effort and get feedback and buy-in. (See above description of MHSRS and EACE meetings. In addition, a poster presentation was prepared and presented for the Eighteenth Annual Research Day at James A. Haley VA Hospital as part of National VA Research Week, May 24, 2016, titled, "Issues Affecting Service Members with Major Limb Trauma." Also, a poster was presented at the annual Rehabilitation Psychology Conference on February 18, 2017, titled, "Psychosocial Challenges Affecting Patients with Major Limb Trauma." A poster was presented at MHSRS on August 29, 2017, titled, "Development of the BADER Toolbox for Measuring Major Extremity Trauma Outcomes in a Military Service Member Population." Finally, a proposal for presentation has been accepted for ACRM for October 28, 2017.)
5. The investigator team spent more than four months preparing for and conducting the upper limb consensus meeting, held on September 26, 2016. Preliminary work included identifying potential invitees to be nominated for each of the consensus meetings to be held. This included several rounds of meetings, discussions by team members with prospective invitees, the compilation of a detailed list of prospects, and nominations submitted by each team member. A compilation of the nominations was sent to the investigator team based on their individual input, and consensus on whom to invite was decided. Letters of invitation were then drafted and sent for the upper meeting, and there was overwhelming and enthusiastic response from invitees, which included specialists of all types who have experience with upper limb trauma and amputation and measurement, as well as military medical leadership, including DoD, VA, and EACE, and academic representation. A 3-hour virtual meeting was held and included 30 external representatives, as well as the Toolbox investigator team. University of Delaware representatives traveled to WRNMMC, CFI, and Naval Medical Center San Diego to participate in person with attendees at those sites (approximately half of the group overall), to help ensure maximum engagement and to directly interact with these attendees and gain their perspectives. At this meeting, we presented materials outlining key decision parameters of a Toolbox (what content domains should be covered, who should administer, what is the maximum time it should take for clinicians and patients, how often and when should the Toolbox be administered), the literature review process, results of the literature reviews and of the qualitative (focus group) study we conducted, and candidate measures for selection in the areas of community reintegration and activity (self-report and performance), as well as amputation-specific measures for that key subgroup. Attendees' preferences were polled on all of these topics e.g., parameters, specific measures to use), using software that allowed them to see the results in real time. We subsequently created a set of recommendations on which attendees were

asked to comment, and the attendees were again anonymously polled on these recommendations. The second set of poll results showed overwhelming support for the recommendations, from all “sectors” of respondents. These measures will, in part, serve as the “Toolbox” to be piloted in spring/summer 2017. The meeting generated positive feedback, with some attendees interested in using information provided during the meeting (e.g., lists of available measures) for other projects, to help make decisions. A similar process was followed for the second consensus meeting, held February 7, 2017, to identify measures of lower limb functioning and health-related quality of life. More than 35 expert stakeholders participated from across the country. A final set of recommendations was devised and a full set of Toolbox measures to be piloted for both upper and lower limb trauma/amputation has been selected and agreed upon.

6. Data collection using the Toolbox has been completed at the three MTFs and at Tampa VA. NMCSO completed its collection with 16 cases, CFI collected 20 cases, and WRNMMC collected 18 cases. Tampa consented 6 participants and completed collection of 5 (the other participant could not complete the assessment due to hurricane). Thus, 60 participants were enrolled as planned, with 59 total cases collected. Quality assurance of all sites’ data entry has now been completed, and data analyses are in process, with planned completion by November 2017. See Appendix E, F, G for materials developed for the Pilot Study of Toolbox. These materials will be further developed and refined as final deliverables at the conclusion of the study.
7. Plans for video training have been fully developed, and we will work in partnership with WRNMMC’s video services team to create professional quality training videos for the performance tests selected as part of the Toolbox. Draft scripts for each measure have been prepared and are being refined. Recording is planned for late November 2017, and will include trained administrators and volunteer participants from WRNMMC, to maximize authenticity. We plan to make these videos available for dissemination at MTFs/VAs as requested for training. A training manual has been developed as well. Based on discussions with the video producer at WRNMMC about their editing and post-production timelines, and given the need for our co-investigators to review and provide feedback, videos should be completed by March 2018.
8. A final investigator meeting is in the early planning phase, with a goal of early 2018, to review final deliverables and data analyses as well as planned next steps in this research.

#### **Publications in Refereed Journals (BADER-related only):**

“Measuring Community Integration in Persons with Limb Trauma and Amputation: A Systematic Review” has been published in *Archives of Physical Medicine and Rehabilitation*. First author is Linda Resnik of the Providence VA.

“Systematic Review of Measures of Impairment and Activity Limitation for Persons With Upper Limb Trauma and Amputation” is in press in *Archives of Physical Medicine and Rehabilitation*. First author is Linda Resnik of the Providence VA.

**Presentations (BADER-related only):**

“BADER Toolbox Overview,” presented by D. Tulsy to EACE, San Antonio, TX, May 17, 2016.

“Selection of Common Assessment Instruments and Data Elements for Individuals with Major Extremity Trauma and/or Amputation,” presented by M. Cohen and D. Tulsy at the Military Health System Research Symposium (MHSRS), August 18, 2016 (Kissimmee, FL).

“Psychosocial Challenges Affecting Patients with Major Limb Trauma,” presented by C. Tyner at the Rehabilitation Psychology Conference, February 18, 2017 (Albuquerque, NM).

“Development of the BADER Toolbox for measuring major extremity trauma outcomes in a military service member population” was presented at MHSRS on August 29, 2017.

**Changes to patient care or other patient impact as a result of the research.**

Patient impact cannot yet be known, as the Toolbox pilot was just completed. Several participant debriefing interviews were conducted at WRNMMC following administration of the pilot Toolbox, and the feedback was generally positive and that the measures can be useful in helping them receive better care. More on this will be provided when ready. In addition, patient experiences were reported as part of our focus groups and qualitative research, and have led to the creation of targeted item pools connected to these patient responses. These patient responses were powerful and impactful in guiding our item development plans.

**Other BADER Facilitated projects related to this work:**

In addition to the BAA-funded project noted above focused on developing item banks, CATs, and clinical score reports, the already-submitted reconstructive hand transplantation grant proposal and a new and similar pre-proposal just submitted, we are considering proposing a similar type of project for VA funding, collaborating with members of EACE. This is still in the discussion phase, as many leaders and collaborators would need to be lined up to be successful.

In addition, there is a clear funding need to conduct a full and formal validation study of the BADER Toolbox, since funding was reduced that would have accomplished that task. As such, we have submitted a PRORP-CTRA proposal, with the goal to have a well-validated, integrated, and feasible set of measures (common data elements) for use in DoD MTFs and VA clinics at regular intervals – and as selected by key stakeholders of these organization. This proposal will also focus on translational activities to initiate formal training protocols for CEU credit and to identify processes for implementation as part of clinical practice guidelines.

**Funding or other opportunities applied for and/or received based on work supported by BADER:**

A DoD BAA proposal, “Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments,” was submitted in April 2016 and funded in the summer of 2017. This work is a follow-on to our qualitative study and focus groups, and will allow the opportunity to create targeted item banks in areas of directly identified need for individuals with traumatic limb injuries.

A follow-up grant for the Toolbox to fully validate it and to initiate translational work at MTF sites, including training and offering CEUs, was submitted on September 27, 2017.

**Submitted but Unfunded Support:**

A USAMRAA (DoD) proposal was submitted in December 2016 in response to a reconstructive transplant research program qualitative research award funding opportunity, titled "Reconstructive Hand Transplantation: Qualitative Approach to Enhance Patient Reported Outcome Metrics and the Candidate Screening Process." This proposal was a partnering PI submission between Dr. Tulsy/UD and Dr. Scott Tintle/WRNMMC, and would capitalize on several of the item banks created and to be calibrated and implemented as part of the DoD BAA project noted above. This proposal was not funded, but a related pre-proposal was submitted in September 2017. The revised proposal has been accepted for full submission and is due December 6, 2017.

### **2014.1 Maximizing Outpatient Rehabilitation Effectiveness (MORE)**

**Abstract:** In 2012, 31.7% of 20,452,769 outpatient visits recorded across the Department of Defense were for rehabilitation services associated with musculoskeletal disorders, the number one cause of disability among active duty service members. Data across all branches of the military indicate that the largest burden of injury from the Global War on Terror is extremity trauma, representing 64% of a projected \$1.9 billion in disability benefit costs, and causing the largest percentage of days on limited duty. Nearly 50% of all extremities injuries involve the lower limb and fewer than 25% of service members with extremities injuries returning to their previous occupation. Service members with lower extremity injuries commonly undergo several months of outpatient rehabilitation in an effort to improve motion, strength and function, and reduce pain and disability. The rehabilitation process for injured service members includes personnel from many different healthcare specialties. Physical Therapists play a major role in the recovery process typically spending more time with the patient than individuals from any other specialty. While treatments interventions are commonly focused on physical deficits, clinicians have long recognized that a multitude of additional factors can affect rehabilitation outcomes. Over the past decade, there has been an increased emphasis on determining which factors affect how well an individual recovers from their injury, how they improve or change during the course of rehabilitation, and whether or not they are likely to fully recover to pre-injury function. Given the current climate of high patient volumes and limited clinical resources, it is increasingly important to characterize persistent deficits and identify predictors of positive and negative rehabilitation outcomes.

In this study, we seek to “(d)etermine factors that predict ... successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment related musculoskeletal injuries.” This study will provide valuable information that can be used to “(d)etermine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or optimize quality of life.” Findings from this study will also help lessen the overwhelming negative impact these injuries have on service members, their families, and our military healthcare system. The proposed study will be conducted with a large group of service members with lower extremity injuries receiving care at three physical therapy clinics at Fort Hood, TX and Joint Base San Antonio, TX. This patient subject group is the exact patient population this study is intended to positively affect, and will result in actionable information to improve current and future clinical care within the military. A range of measures that characterize physical deficits, functional limitations, activity restrictions, and health related quality of life will be collected by clinical research staff fully imbedded within the physical therapy clinics of Fort Hood, TX and Joint Base San Antonio, TX. This approach not only ensures that a large percentage of service members with extremity injuries at these clinics will be enrolled, but that also enhances the ecologic validity of this study. Physical, cognitive, and psychosocial measures will be administered in parallel with rehabilitative care. There are three primary sources of data in this proposed study: 1) self-report surveys, 2) participant medical records, and 3) physical assessments. Imbedded clinical research staff will directly observe, measure, record, and report functional changes that occur throughout the rehabilitation processes at each of these sites. Assessments metrics contained in the National Institutes of Health’s (NIH) Patient Reported Outcomes Measurement Information System (PROMIS) will be leveraged for this study and electronically collected with additional outcome metrics using computer tablets (i.e. Apple iPads). De-identified data will be entered into the BADER Clinical Trials Database system for analysis.



An improved understanding of the types and magnitudes of deficits present, and their relative contributions to treatment success, goal attainment, and health related quality of life in a military setting is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness. As final study results become available, information will be directly shared with treating therapists through incorporation into educational programs to promote evidence based practice and accelerate patient recoveries.

Title:	2014.1: Maximizing Outpatient Rehabilitation Effectiveness (MORE)	
Funded Amount:		
Principal Investigator:	Amy Bowles, MD	Brooke Army Medical Center, Center for the Intrepid
Collaborators:	Jason Wilken, Pt, PhD	University of Iowa
	David Tulskey, PhD	University of Delaware
	COL Scott Shaffer, PhD	Joint Base San Antonio TX
	MAJ Sean Suttles, PT, DPT, OCS	Fort Hood, TX
	Paul Kolm, PhD	Christiana Care, Newark Delaware
	MAJ Owen T. Hill, PhD	Center for the Intrepid, Joint Base San Antonio

Subject Accruals:	Potential subjects contacted: 200+ Potential subjects screened: 154 Subjects enrolled: 154 total (136 patients, 18 therapists)
IRB Approvals:	Expires December 19, 2017

### **Research Progress Update:**

**Specific Aim 1: To determine factors that predict clinical outcomes following outpatient rehabilitation in a military setting.** Information collected at the initial visit and early in the treatment process will each be used to predict and identify factors that influence discharge values for 1) patient and therapist reported improvements and goal attainment, 2) objective measures of physical capacity/ability and 3) health related quality of life. Measures include impairment level variables (e.g. strength and range of motion), performance on objective tests of physical activity, psychosocial factors (e.g. self-efficacy) and therapist related factors (e.g. experience).

a) Enrollment of therapist and patient participants and subsequent data collection is ongoing at all orthopedic and physical therapy clinics. Subject recruitment at the CFI continues to be a challenge due to lack of subjects meeting enrollment criteria. Continued attempts are being made to familiarize therapists with study dependent measures and the patient data collection process. Obtaining Goal Attainment Scale data from therapists has been challenging. Data review and quality checks are ongoing.

b) New personnel have been hired to the study staff. The robust study procedure manual will continue to facilitate the rapid training and integration of the new study staff. Multiple practice sessions will be conducted to ensure consistency and accuracy while awaiting approval of IRB amendments to add the staff. Once IRB amendments have been approved, identifying and recruiting study subjects into the study will be a primary focus of activities for the next quarter.

c) The transition of Dr Wilken to the University of Iowa and the handoff to Dr Bowles as PI has resulted in only minor disruption of study activities. Per his written transition plan, Dr Wilken will continue to play an active role in the study. The subaward to Iowa for the study has taken longer than expected to complete.

d) Please see above.

**Specific Aim 2: To determine the extent to which patient reported and observed outcomes change and covary during the course of outpatient rehabilitation.** Function of the limb, objective assessments (impairment and physical activity measures) and subjective reports of physical ability along with symptomatology are used to assess recovery following musculoskeletal injury. The extent to which these measures and psychosocial factors covary and change during the course of rehabilitation is largely unknown. We will use data from the initial visit, quarter-point, half-point and discharge to determine the extent to which measures change over the course of care and determine if between-measure associations change over the course of care.

a) See above Aim 1a.

b) See above Aim 1b.

c) See above Aim 1c.

d) See above Aim 1d.

**Specific Aim #3. To determine the magnitude of residual deficits following completion of outpatient rehabilitation.** Military physical therapists typically work with their patients until they can successfully return to their desired activities and/or have reached a maximal level of recovery. However, the decision to conclude therapy is most commonly made using therapist and patient self-reflection with limited data establishing the expected or maximal rehabilitation outcome for individuals with similar injury characteristics. We will use data collected at the completion of care to determine the prevalence of residual biopsychosocial deficits.

a) See above Aim1 a.

b) See above Aim1 b.

c) See above Aim1 c.

d) See above Aim1 d

**Study Completion Projection:** 9/30/2019 with a second 2-year NCE. Enrollment has been delayed due to lack of staffing. The University of Iowa has been added to the study as a site for enrollment to achieve desired study numbers. The NCE will be required to complete collection, data analysis and finalization of study activities.

Significant delays associated with the human subjects regulatory process, when added to the delay in receipt of funds, put the project behind schedule. As a result, it will take at a minimum, the entirety of the one year no-cost extension to complete the study. Although, as described in the proposal, many efforts were completed prior to receipt of funds, several factors have prevented timely progress. In addition to systemic regulatory delays associated with the loss of IRBNet, the local IRB failed to send our initially approved protocol to HRPO for second tier review delaying initiation of patient recruitment. The initiation of a new eIRB system has resulted in additional regulatory delays. We have recently added staff and are actively working to make up for lost time.

## **Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation**

**ABSTRACT:** Our work is motivated by the lack of objective criteria for evaluating and prescribing prosthetic ankle-foot components for Service Members with transtibial amputations wishing to perform load carriage and other physically demanding tasks. Healthy intact ankle-foot systems adapt to added load by maintaining similar ankle motion and effective rocker shapes during walking. In contrast, most prosthetic feet are spring-like and continue to bend with added load, suggesting they may not mimic the physiologic system they are trying to replace during weighted walking. Additionally, there are currently no data to suggest which types of prosthetic feet will be most resistant to breakage during impact loading (e.g. loads that would be experienced when jumping off of a Humvee). We expect that mechanical testing will show a large diversity of mechanical properties of prosthetic feet based on marketing materials (some companies market extreme flexibility while others market limited flexibility). For the testing in Aim 2, we expect that the more flexible prosthetic foot (one that deforms considerably with added weight) will lead to increased loading on the intact limb during walking compared with the less flexible prosthetic foot. The planned testing will provide quantitative data to support the selection of prosthetic feet for highly active Service Members with lower-limb amputations, including data on impact durability and response to added loads above body weight. Prosthetic feet that can reduce loading to the intact limb may be prescribed to reduce the chances for long-term secondary complications of the intact limb (e.g. knee osteoarthritis). Although studies have been conducted on weighted walking in able-bodied persons and persons with lower-limb amputations, none have examined the effects of different prosthetic foot properties on gait. This study is innovative in that it combines the use of mechanical testing, functional testing, and clinical testing of prosthetic feet for persons in the highest functional levels. This comprehensive investigation should greatly improve our knowledge of these types of prosthetic feet and have direct implications for their prescription.

Title:	2014.2: Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation	
Funded Amount:		
Principal Investigator:	Barri Schnall, MPT	Walter Reed National Military Medical Center
Collaborators:	Andrew Hansen, PhD	Minneapolis VA, University of Minnesota
	Bradford Hendershot, PhD	Walter Reed National Military Medical Center
	Joan Bechtold, PhD	University of Minnesota
IRB	Expires: March 10 2018	
Subject Accruals:	Minneapolis VA: Patients contacted: 3 Patients screened: 3 Patients enrolled: 3	WRNMMC: Patients contacted: 20 Patients screened: 16 Patients enrolled: 13

### **Research Progress Update:**

For each aim, describe: (a) what you have done, (b) what the next steps will be, (c) the administrative and scientific challenges you have experienced and (d) what you are doing to overcome them.

**Specific Aim 1:** Determine mechanical characteristics and durability of current prosthetic feet intended for highly functional transtibial prosthesis users.

- a) **We have completed Major Task 1** – Mechanical stiffness characterization of prosthetic feet. **We have completed Major Task 2** – Roll-over shape characterization of prosthetic feet. **We have completed Major Task 3** – The drop tester device has been completed and validation results have been analyzed and submitted as an abstract. Prosthetic feet have been dropped from various heights, with additional measurements obtained using the impact load cell.
- b) Next steps will be to generate a manuscript to disseminate results from Major Task 3– Impact durability characterization of prosthetic feet. We have been invited to submit a manuscript as part of a recent presentation at the O&P World Congress.
- c) n/a
- d) n/a

**Specific Aim 2:** Compare biomechanical and functional outcomes between prosthetic feet with linear and non-linear mechanical properties (“stiffness”) during weighted walking and high-intensity (CHAMP) activities.

- a) Human subjects testing in Specific Aim 2 has been approved by the WRNMMC IRB and HRPO. 16 participants have been consented, 13 have been fully collected, 1 was not included in data analysis, and 2 withdrew from the study.
- b) Recruit and collect the final participant, finalize data analysis, and prepare manuscript for publication.
- c) None, other than the requirement of additional funds to purchase prosthetic feet in SA2, though this issue has been resolved and a path forward identified.
- d) n/a

**Publications in Refereed Journals (BADER-related only):**

Koehler-Nicholas, S.R., Nickel, E.A., Barrons, K., Blaharski, K.E., Schnall, B.L., Hendershot, B.D., Hansen, A.H. Mechanical Characterization of Prosthetic Feet for Weighted Walking. In preparation for submission to *Journal of Biomechanics*

**Presentations:**

Golyski, P.R., Schnall, B.L., Hendershot, B.D. Biomechanical Implications of Prosthetic Foot Stiffness For Loaded Walking. Poster presentation at Walter Reed National Military Medical Center 9<sup>th</sup> Annual National Capital Region Research Competition

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. Biomechanical Outcomes of Prosthetic Foot Stiffness During Weighted Walking. Poster presentation at 41<sup>st</sup> Annual Meeting of the American Society of Biomechanics

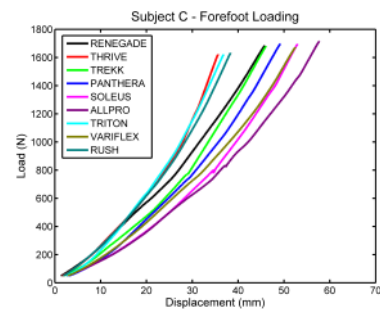
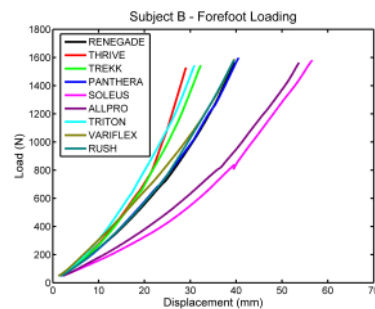
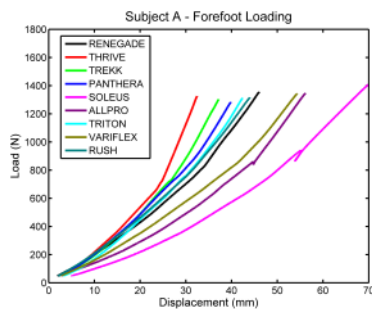
Eric Nickel, Steve Morin, Gregory Voss, Sara Koehler-McNicholas, and Andrew Hansen. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Poster presentation at Military Health System Research Symposium.

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. Biomechanical Implications of Prosthetic Foot Stiffness for Walking with Added Load. Poster presentation at Military Health System Research Symposium.

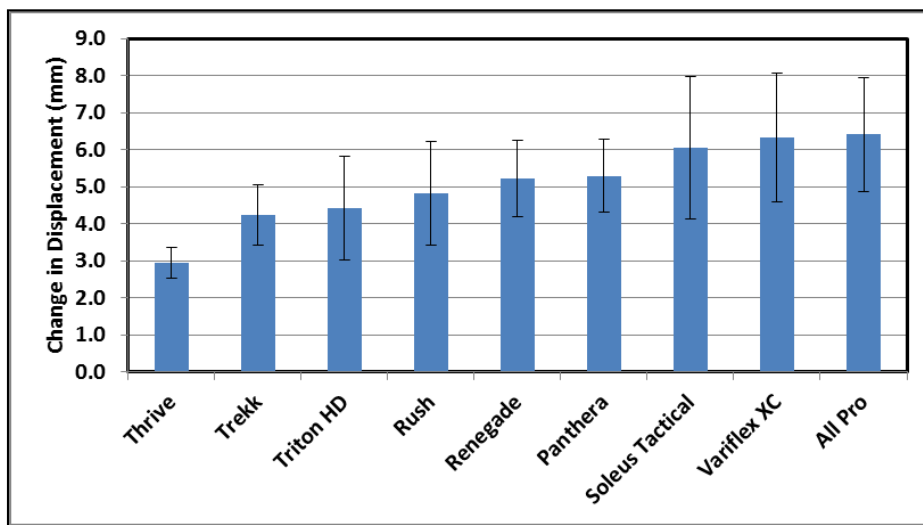
Eric Nickel, Steve Morin, Gregory Voss, Sara Koehler-McNicholas, and Andrew Hansen. Impact test for Prosthetic Feet. Podium presentation at 2017 O&P World Congress.

### **Preliminary results:**

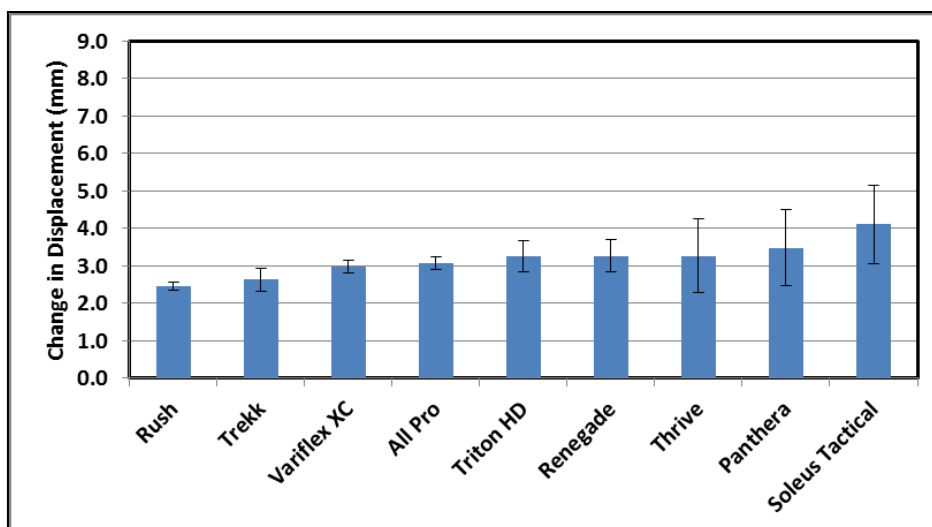
**We have completed Major Task 1** - Major Task 1 (Mechanical stiffness characterization of prosthetic feet) was accomplished at Excelen Biomechanics Laboratory in Minneapolis, Minnesota; with data analysis completed at the Minneapolis VA. The images below show the testing set-up for forefoot loading within an MTS load frame. All 27 prosthetic feet were tested within military boots. Forefoot sections of prosthetic feet were tested at a 20 degree angle and heels were tested at a 15 degree angle to mimic the ISO 10328 testing standard. As expected, we found a high variance in forefoot stiffness properties.



In addition, we have determined the change in displacement associated with adding 49lbs of added weight:



Change in displacement due to 49lbs of added load to the forefoot (loading angle = 20 degrees)

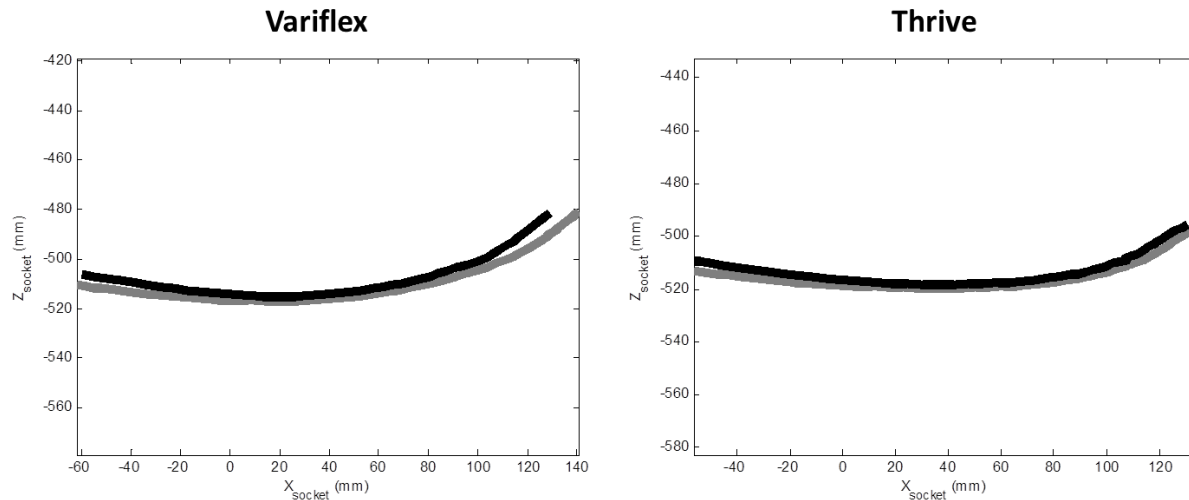


Change in displacement due to 49lbs of added load to the heel (loading angle = 15 degrees)

The results suggest that there are larger changes in forefoot properties between feet compared with heel properties. As expected, the Thrive prosthetic foot yields the lowest additional forefoot displacement when loaded above body weight. All Pro, Variflex, and Soleus Tactical have the largest additional displacements on the forefoot when loading above body weight.

**We have completed Major Task 2** - We have completed subtask 2.1 – Rollover shape measurements of 3 Veterans with unilateral transtibial amputations, each using 9 different types of feet, while loaded and unloaded. The data have also been processed and fitted with circular arc models. Milestone 2 (Roll-over shape

data collected for 27 prosthetic feet for loaded and unloaded walking) has been completed. Two examples are shown below:



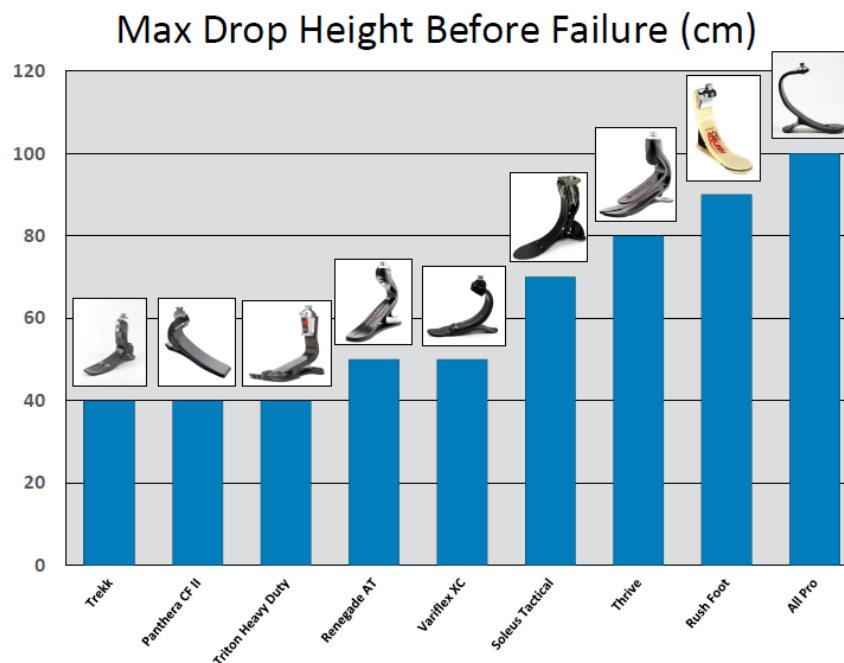
There is a trend for a reduction in radius of the roll-over shapes due to added weight carriage; however, the amount of change in radius does not seem to correlate with changes in displacement due to the added weight. This suggests that the small changes in mechanical properties are either not important or that the user is adapting to differences in mechanical properties to maintain similar roll-over shape radii between foot conditions. The larger study in Aim 2 should help to further our understanding.

Based on the results of the mechanical testing, we are recommending use of the Thrive as the “non-linear” prosthetic foot in Aim 2. We are also recommending the use of either the All Pro, Variflex, or Soleus Tactical as the more linear foot in Aim 2. Discussions within our groups have swayed toward using only Major Tasks 1 and 2 results to determine the prosthetic feet to use in the study. The reason for this approach is that the Aim 2 study at Walter Reed will inform our understanding of prosthetic foot mechanical properties on function of the user. Durability issues that may arise with current designs will influence prosthetic choices later and may lead to design revisions, but these issues should not interfere with our study aimed at gaining an understanding between mechanical and functional properties of feet. We believe that finding the best functioning foot for return-to-duty is important and that any durability issues that may arise with a best-functioning foot may be addressable through future design revisions.

**Major Task 3:** The drop tester for assessing impact durability characterization of prosthetic feet has been constructed. Validation results demonstrate the device effectively replicates free fall – Standard deviation of drop height measurement was 0.06mm within 1 rater, and 1.4mm between 3 raters.



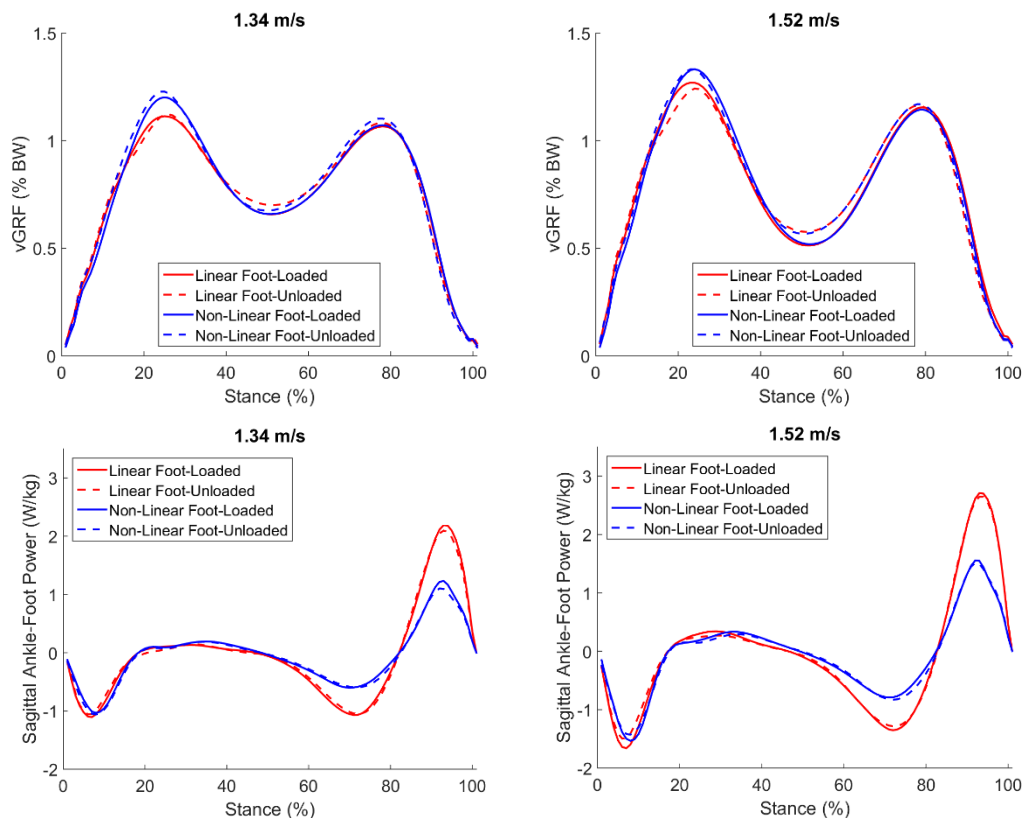
Prostheses failed at a drop heights ranging from 0.4m to 1.0 m. At the lowest drop height, the difference between potential energy at the drop and impact energy calculated using velocity at impact was 4.7%. Additional results using the impact load cell are forthcoming.



**Major Task 4:** Full biomechanical and functional data from Specific Aim 2 are process/analyzed for 13 participants. In contrast to our hypotheses, preliminary results indicate larger first peak vertical ground reaction forces on the intact limb with the foot with non-linear (Thrive) vs. linear (Soleus Tactical) stiffness, while first peak prosthetic limb loads did not differ by foot. However, the mechanical characterization of the two prosthetic feet accomplished in Major Task 1 may explain this observation, since the non-linear foot (vs. linear foot) exhibited larger stiffness values both below and above body weight. Such larger stiffnesses can translate to



decreased energy storage and return over stance and decreased push off on the prosthetic foot, which has been associated with larger intact limb loads. An analysis of prosthetic foot power further substantiates this revised hypothesis. Intact limb vertical ground reaction forces and prosthetic foot powers from the 13 fully processed study participants are shown below:



## **Key Research Accomplishments**

**FOR THE PERIOD**

**SEPTEMBER 30, 2011 – SEPTEMBER 29, 2016**

**BADER Consortium**

**W81-XWH-11-2-0222**

**Annual Report – Year 6**

**Key Research Accomplishments**

**Key Accomplishments in the sixth year of performance (September 30 2016 – September 29 2017):**

- The BADER consortium publication count reached 84 published abstracts/presentations and 21 published manuscripts this year. Additionally, 1 manuscript is in revision and 4 are in process.
- Three CRC staff (Wingate, Hiebert, Hulcher) presented abstracts at the MHSRS conference August 2017.
- Updated quad charts for all BADER funded studies are included in Appendix D.
- Dr. Jason Wilken resigned from the CFI and with the assistance of the BADER Consortium, completed his transition to the University of Iowa. The BADER Consortium will continue to work with all affected project PIs to implement desired and required project administrative adjustments to affected BADER funded projects.
- In spite of staff cutbacks, the BADER Consortium provided support for 16 Military Treatment Facility (MTF) non-BADER funded research projects and 7 related activities (see Appendix C). Other contributions of the BADER Consortium towards MTF research capabilities included drafting protocols for both CAREN and gait labs, creating an Access database for tracking projects and products, preparing reports for the Extremity Amputee Center of Excellence (EACE), assisting with literature searches, conducting of training sessions on equipment and performance measures.
- The BADER Consortium led efforts to establish, edit and publish the Military Medicine supplement, Volume 181, November/December 2016, pp. 1-80 titled “Raising the Bar: Extremity Trauma Care”.
- The BADER Consortium currently coordinates and manages Institutional Review Board (IRB) documentation activities for 23 protocols (15 active; across 9 investigators).
- The BADER Consortium established a method for holding virtual consensus meetings. As a result, 47 individuals from across the country – including MTF sites - were able to simultaneously participate in a major BADER funded Measurement Consensus Meeting.
- The Outcomes Measurement Library for BADER-relevant outcomes measures has been established. The library has been updated with recent publications. This information has been provided to the BADER CTDB team to see how this work could be integrated with the Clinical Trials Database and used as a

central research and patient care tool. Permissions have been obtained for 22 of the measures to be included thus far.

- During this period of performance, several grants related to BADER funding were submitted and awarded. The BADER Consortium has nearly seven million dollars in research proposals among various agencies pending review and awarding.
- Dr. Tulskey's BAA "Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments" has been awarded in the amount of \$4 million
- This year, the BADER Consortium supported the submission of 17 grant applications across three of the MTF sites (NMCP, WRNMMC, and NMCSD). Not having oversight authority, the BADER Consortium receives little submission detail and follow-up information on these applications. In contrast, non-DoD investigators appear to provide substantial details.

**Key Accomplishments in the fifth year of performance (September 30 2015 – September 29 2016):**

- Spearheaded two AMSUS Publications for Military Medicine
- Established relationship with Thought Leadership Innovation Foundation
- Supported the submission of two BAA proposals
- Established agreement to use NIH BRICS system – a more robust protocol and data management system
- MORE project fully modeled in CTDB
- BADER Consortium highlighted in Military Medicine Supplement
- Clinical Research Core staff coordinated 20 protocols at Center for the Intrepid
- Clinical Research Core staff supported 38 research projects and 11 related activities at the MTFs
- Clinical Research Core staff submitted four abstracts to the 2016 MHSRS call for abstracts
- Supported continuing education for CRC staff – two in the Masters in Public Administration Program and one in the MBA program.
- Biomechanics Core published a new gait symmetry index in the Journal of Applied Biomechanics based on work done with the BADER Consortium
- Outcomes Measurement Core completed systematic review of 32 measures of physical functioning
- Outcomes Measurement Core established a measurement library for BADER relevant outcomes measures
- Outcomes Measurement Core delivered training materials related to PROMIS
- The BADER Consortium began showing signs indicating significant maturation and advancement of research efforts at our partner MTF and VA sites.
- This quarter, greater than \$7.1M in grant proposals were submitted.

- Research support provided by BADER Clinical Research Core staff – located at each MTF site – expanded to include research support for 37 non-BADER-funded studies.
- The BADER Consortium received approval from HRPO to start the eighth BADER-funded project (Ruck-Foot at WRNMMC).
- With only one completed BADER-funded project, BADER has produced five published manuscripts and 44 published abstracts.
- The BADER Consortium has been asked to facilitate engaging MTF sites in industry sponsored and FDA approved clinical trials.
- NMCP team has fully established a novel research paradigm for studying the occurrence and rehabilitation of musculoskeletal injuries under an aircraft carrier deployment model.
- The biofeedback paradigm tested under the return-to-run BADER-funded study has been transitioned to use in the clinic at WRNMMC.
- The gait stability research initiative has officially launched. It is based on findings from the Step2Step BADER-funded project. Results from the Step2Step project indicate the “Rehab Frogger” paradigm is an effective rehabilitation training intervention to enhance the ability of patients to optimize their stepping control strategies to maximize both stability and maneuverability. The gait stability research initiative has substantially advanced - receiving an R01 award this quarter from the NIH to further study the impact of the “Rehab Frogger” paradigm.
- In addition, the gait stability team has recently launched a new initiative to develop and investigate the effectiveness of a low-cost and clinically applicable (CAREN-light) version of the CAREN system located at several of the MTF sites. The initiative involves MTFs, industry and academia. The CAREN-light system will provide MTF and VA clinics access to the “Rehab Frogger” paradigm.
- The RAPIDFab initiative began as a 3D printing AFO study that was originally proposed by the BADER Consortium - but not allowed to proceed by the Government Steering Committee.
- The RAPIDFab initiative has generated over \$3.5M in subsequent grant awards, six publications and thirteen published abstracts. The RAPIDFab team, led by Dr. Wilken at the CFI, is planning its next major grant submission.
- The Outcomes Core is preparing to execute an outcomes consensus conference expected to attract a global sample of rehabilitation outcomes experts.
- In addition, the Outcomes Core has developed and submitted a BAA proposal for substantially advancing the tool box of identified outcomes measures as agency wide research and patient care tools.
- The BADER supplement to Military Medicine – International Journal of AMSUS was published in February 2016. The supplement reports on activities related to the first, “WARfighters Receiving Innovative Orthopedic Rehabilitation (WARRIOR) Symposium: Research and Treatment of Patients with Extremity Trauma and Amputation,” which was sponsored by the BADER Consortium and held in San Antonio, Texas on 30 November to 4 December in conjunction with the 2015 AMSUS Meeting.
  - [http://publications.amsus.org/pb-assets/Supplements/181\\_2\\_Supplement.pdf](http://publications.amsus.org/pb-assets/Supplements/181_2_Supplement.pdf)
- With the news that the proposal to continue BADER efforts was not recommended for funding, BADER transitioned to the new BADER committee structure that positions Drs. Wilken and Kaufman as co-chairs of the BADER Consortium Committee. The committee is focused on completion of current projects and

sustainment efforts centered on the further establishment of externally funded research initiatives and the termination or transition of BADER components to EACE or MTF management.

- BADER has begun eliminating staff and terminating support for core resources in alignment with its sustainment and transition plan.
- Successful AMSUS meeting and creation of strong partnership
- Discussions with EACE to strengthen partnership
- Worked with MTF staff to develop a universal research support and capacity building model
- Identified several large scale research initiatives
- Worked with MTF representatives to develop an adapted Statement of Work and No Cost Extension budget
- Established enhanced partnership with NIH for the use of the BRICS system

#### **Key Accomplishments in the fourth year of performance (September 30 2014 – September 29 2015):**

- Eight identified BADER funded studies are active and collecting subject data.
- BADER Scientific Technical Cores supported six MTF proposals
- BADER Clinical Research Core staff are supporting 64 projects at the MTFs. This is a combination of BADER-funded and non-BADER funded projects.
- The CTDB now has six active protocols for Consortium funded projects and study data for seven subjects has been entered
- The Collaboration Agreement between the UD and the NIH for use of the CTDB was renewed for an additional two years
- Training materials related to the CTDB were finalized and uploaded to a secure site for staff use
- CRC staff member Dr. Steve Jamison submitted his first white paper to the Fall 2014 CDMRP call for proposals and was invited to submit a full proposal
- MTF representatives have embraced the concept of creating a large-scale, nationwide Human Subject Recruitment Campaign
- Dr. David Tulskey relocated to the University of Delaware to lead Outcomes Measurement initiatives
- Policies are being developed at the University of Delaware to allow non-University personnel to be PIs on research proposals submitted through UD
- Four Clinical Research Core staff had abstracts accepted for the 2015 MHSRS Conference.
- Eight abstracts were submitted to MHSRS.
- Received Subaward with NYU on the NMCP project **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries”**
- Fully executed subcontract with the first BADER-METRC Collaboration **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”**

#### **Key Accomplishments in the third year of performance (September 30 2013 – September 29 2014):**

- Approval of two additional BADER funded research projects bringing the total to 8
  - Project 2014.1 – Maximizing Outpatient Rehabilitation Effectiveness (MORE)
  - Project 2014.2 – Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower Limb Amputation
- Successfully filled all vacant BADER funded staff positions at the MTFs
- Provided research support to over 24 non-BADER funded on-site protocols at the MTFs
- Began exclusive partnership with Leidos on Homeland Defense TATs IDIQ mechanism
- Established a collaborative agreement with NIH for the use of the CTDB and modeled two protocols in the system.
- Presented the BADER Consortium to the Defense Health Board, Health Care Delivery Subcommittee on May 21, 2014
- Enrolled first MTF staff member into Biomechanics and Movement Science PhD program at the University of Delaware.
- Established a policy at the University of Delaware for external PIs
- Developed a process for receiving donations for research support
- Multiple (n=6) BADER-supported proposals recommended for funding
- First BADER-METRC Collaboration proposal recommended for funding
- Omnibus CRADA dramatically streamlining project initiation
- IRB – HRPO process is improved
- CTDB being implemented on a large scale across Consortium
- WRNMMC received approval to recruit non-military, civilian human subjects
- Initiating nationwide Human Subjects Recruitment Initiative
- Realized an uptick in additional grant submissions and funded projects across the Consortium
- Planning underway for Orthopaedic Rehabilitation Research Annual Meeting
- BADER Operations model finalized

**Key Accomplishments in the second year of performance (September 30 2012 – September 29 2013):**

- Approval of three additional BADER funded research projects bringing the total to 5:
  - Project 2012.2 – Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback.
  - Project 2012.1 – Improving Step-To-Step Control of Walking in Traumatic Amputees.
  - Project 2013.1 – Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?
  - Project 2013.2 - Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.
  - Project 2013.3 - Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.
- Recruited all eight BADER funded positions at the MTFs
- Provided research support to nine on-site MTF research projects.

- IT and videoconference infrastructures
- Continue to increase the ranks of BADER Consortium Affiliates (n=96)
- Support NMCS D with use of UD Power Segment technique
- Streamlined the IRB approval process by establishing blanket Institutional Award Agreement (IAA).
- In concert with the MTFs, began development of a central research subject repository.
- Held the first BADER Consortium annual meeting.
- Providing valuable research support through Consortium funded on-site employees.
- On-boarded multiple agencies to the omnibus CRADA to reduce administrative hurdles and allow rapid execution of research studies.
- Established a research related travel support policy and supported travel expenses for collaborators to visit MTF sites and two MTF personnel to present at the American Society of Biomechanics (ASB) scientific meeting.
- Supporting multiple proposals for external funding.
- Strengthen research collaborations and partnerships between MTFs, VA and research focused institutions.
- The live instance of the NIH supplied Protocol and Data Management System (PDMS) is up and running on BADER servers.
- Development of table and announcement for alternative project funding models.
- Strategizing with NIH officials.
- Outreach and meetings with VA.
- BADER Consortium Web-site development continues:
  - Secure log-in to the website completed
  - Core services request form completed
  - Additional enhancements being explored

**Key Accomplishments in the first year of performance (September 30 2011 – September 29 2012):**

- Approval and establishment of two clinical research projects
- HRPO clearance and start of first project (Dingwell)
- Initiated the development of first IRB of record outside the MTFs (Davis)
- Initiated the development of partnership with Nike, USA (Davis)
- Development and implementation of an Omnibus Cooperative Research and Development Agreement (CRADA)
- Established a consortium-wide protocol and data management system
- Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE)
- Worked with the EACE to develop research focus (gap) areas for the BADER Consortium call for proposals
- Established a complete process for the call, submission, review and selection of Consortium funded projects
- Published the BADER Consortium call for clinical research proposals
- Established the BADER Consortium web site and standard operating procedures (SOPs)



- Initiated the hiring of eight research support staff to be placed onsite at MTFs.
- Open communication with all MTFs and partners through bi-weekly teleconferences
- Established partnerships with the VA and NIH

**Reportable Outcomes**  
for the period  
September 30, 2011 – September 29, 2017:

## ***Research Projects:***

### **BADER Funded Projects:**

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** . Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Pruziner, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** . Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”** . Sites: Eastern Colorado Healthcare System – Department of Veterans Affairs, Jewell Regional Amputation Clinic.

Pruziner, A., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”** . Sites: Walter Reed National Military Medical Center, Hunter Holmes McGuire VA Medical Center.

Tulskey, D., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”** Sites: New York University, University of Michigan, Walter Reed National Military Medical Center, Brooke Army Medical Center/Center for the Intrepid, Naval Medical Center San Diego, NYU Langone Medical Center, Providence VA Medical Center, James A. Haley Veterans Hospital, Tampa FL.

Wilken, J., Tulskey, D., Shaffer, S., Houck, K., Hill, O. **“Maximizing Outpatient Rehabilitation Effectiveness (MORE)”**. . Sites: Joint Base San Antonio, TX; Ft. Hood, Killeen TX; University of Delaware.

Schnall, B., Hansen, A., Hendershot, B., Bechtold, J. **“Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation.”** . Sites: Walter Reed National Military Medical Center; University of Minnesota; Minneapolis VA.

### **BADER Scientific Technical Core Supported projects:**

Tulskey, D., Wyatt, M., **“A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma.”** Sites: University of Michigan, Naval Medical Center San Diego, Brooke Army Medical Center/Center for the Intrepid.

### **Externally Funded Projects Supporting BADER Activities or Supported by BADER:**

Tulskey, David: **“Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments.”**

Ziemke GW, Campello M, Rennix CP, et al. **“Retrospective Administrative Limited Duty Outcome Review”**  
Lovelace Respiratory Research Institute; 2012. Contract Number 2011.029.

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”**  
Proposal to CDMRP/PRORP, July 2013. Recommended for funding, awaiting subcontract. This is a  
METRC/BADER Collaboration.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training  
for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July  
2013. Sites: NMCP, NYU.

Gillespie, J., et al. **“Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses Designs for  
Wounded Warriors.”** . Sites: University of Delaware. Funded by: DARPA

Whittelsey, S., Selbie, W.S. **“Development of a Low Cost, Real-time Biofeedback Gait Retraining  
System”** . Funded by: NIH, Phase I – SBIR. Sites: C-Motion, LLC

Kaufman, K. **“Comparison of 3-D Gait Analysis Data Across Department of Defense Sites.”** Funded by: Center  
Rehabilitation Sciences Research (CRSR). Support by Biomechanics Scientific Technical Core. Sites: Mayo Clinic,  
MTFs

Deluzio, K. J., Selbie, W.S., **“Statistical Models for Establishing a Control Data Set for Biomechanical Gait  
Analysis”** . Natural Sciences and Engineering Research Council of Canada.

#### **Pending Proposals for External Funding Supported by BADER:**

CDMRP PRORP W81XWH-17-PRORP-CTRA (Grabowski) 01/01/2018 – 12/31/2020  
Department of Defense Total award amount:

**Project Title:** Optimizing the Alignment and Performance of Running-Specific Leg Prostheses

**Short project description:** We propose to quantitatively study the effects of different running-specific prosthetic  
sagittal plane alignments on running and sprinting performance in Veterans and service members with  
transtibial amputations and integrate these findings into clinical best practices for optimal prosthetic  
prescription.

CDMRP PRORP W81XWH-17-PRORP-CTRA (Grabowski) 01/01/2018 – 12/31/2020  
Department of Defense Total award amount:

**Project Title:** Does Use of a Powered Ankle-Foot Prosthesis Improve Physical Activity?

**Short project description:** We intend to compare the physical activity duration and intensity of Service members  
and Veterans with a transtibial amputation using a passive-elastic and the BiOM prosthesis to a non-amputee  
cohort.

CDMRP PRORP W81XWH-17-PRORP-ATA (Grabowski) 01/01/2018 – 12/31/2020  
Department of Defense Total award amount:

**Project Title:** Optimizing prosthetic prescription for running in Service members with transfemoral amputations

**Short project description:** The overall goal of this project is to develop objective guidelines for prescribing running-specific prostheses to Service members, Veterans, and civilians with transfemoral amputations.

CDMRP ORORP W81XWH-16-OPORP-PORA (Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Optimizing the Alignment and Performance of Running-Specific Leg Prostheses

**Short project description:** We propose to quantitatively study the effects of different running-specific prosthetic sagittal plane alignments on running and sprinting performance in Veterans and service members with transtibial amputations and integrate these findings into clinical best practices for optimal prosthetic prescription.

CDMRP DHA-17-CR11-MWHRA (Wyatt/Grabowski) 01/01/2018 – 12/31/2020

Department of Defense

Total award amount:

**Project Title:** Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation

**Short project description:** The goals of this project are to determine how the stiffness and weight of an orthosis (IDEO) or running-specific prosthesis effect the running performance and preference of female Service members with limb salvage or leg amputations.

#### **Research Proposals - BADER Supported**

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013.

Judkins, T. **“Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.”** Proposal to Department of Defense SBIR, June 2013.

Ziemke, G., Campello, M. **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”** Proposal to CDMRP/PRORP, July 2013.

Ziemke, G, Campello, M.; Hiebert, R; Faulkner, DF. *Backs to work study – \$500K BUMED*

Ziemke, G, Campello, M.; Hiebert, R; Faulkner, DF *ACDA/ACDF study – \$350K BUMED*

Ziemke, G, Campello, M.; Hiebert, R; Faulkner, DF *Attrition study – \$120K BUMED*

Ziemke, G, Campello, M.; Hiebert, R; Faulkner, DF *Carrier study – CDMRP \$1.02 mil*

Ziemke, G. **“Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion for Spinal Post-Traumatic Osteoarthritis”**. CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, G. **“Identifying Obstacles and Facilitators of Work Re-Integration in Active Duty Sailors and Marines with Deployment and/or Combat-Related Musculoskeletal Injuries.”** CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, Gregg: "Factors associated with duty status outcomes in sailors who suffered musculoskeletal injuries during operational and combat related deployments".

Stanhope, S. **“BADER Consortium – A Five Year Budget Projection”** proposal for sustaining Consortium Operations. Submitted July 16, 2014 to the Health Care Delivery Subcommittee of the Defense Health Board.

Buchanan, T. **“OA study.”** CDMRP/PRORP pre-application, not invited for full submission.

The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.

The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.

Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD, project and wishes to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.

## **Manuscripts, abstracts, presentations**

### **BADER Funded Projects**

#### ***Publications:***

Beck, ON, Taboga, P & Grabowski, AM. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? 14: 20170230. Published 28 June 2017. Royal Society Interface DOI: 10.1098/rsif.2017.0230

Beck, ON, Taboga, P & Grabowski, AM. Prosthetic model, but not stiffness or height, affects the metabolic cost of running for athletes with unilateral transtibial amputations. Published March 30, 2017. Journal of Applied Physiology <http://jap.physiology.org/content/early/2017/03/28/jappphysiol.00896.2016>

Beck, ON, Taboga, P & Grabowski, AM. Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. Published Jan. 19, 2017. Journal of Applied Physiology DOI: 10.1152/jappphysiol.00587.2016

Beck, ON, Taboga, P & Grabowski, AM. Characterizing the mechanical properties of running-specific lower-limb prostheses. *PLoS ONE* 11(12): e0168298. doi:10.1371/journal.pone.0168298, 2016.

Bothum KM, Bogan-Brown KL, Cecere FA. Proceedings of the AMSUS Summit for Federal and Civilian Orthopedic Rehabilitation Programs *Military Medicine*, 2016 Feb;181(S2):3-10.

Cecere FA, Stanhope SJ, Kaufman KR, Oldham BW, Shero JC, Mundy JA, guest editors, Raising the Bar: Extremity Trauma Care. *Military Medicine supplement* 2016 Nov;181(S4):1-80.

Cecere FA, Oldham BW. "Raising the Bar" in Extremity Trauma Care: A Story of Collaboration and Innovation. Editorial. *Military Medicine* 2016 Nov;181,11/12:1-2.

Dingwell JB, Cusumano JP. Identifying Stride-To-Stride Control Strategies in Human Treadmill Walking *PLoS ONE*, 2015;10(4): e0124879. (Published on line 04/24/15: <http://dx.doi.org/10.1371/journal.pone.0124879>).

John J, Dingwell JB, Cusumano JP. Error Correction and the Structure of Inter-Trial Fluctuations in a Redundant Movement Task *PLoS Computational Biology*, 2016;12(9): e1005118. (Published on line 09/19/16: <http://dx.doi.org/10.1371/journal.pcbi.1005118>).

Farrokhi S, Mazzone B, Yoder A, Grant K Wyatt M. A narrative Review of the Prevalence and Risk Factors Associated With Development of Knee Osteoarthritis After Traumatic Unilateral Lower Limb Amputation. *Military Medicine* 2016 Nov;181, 11/12:38-44.

Kaufman KR, Stanhope SJ, Oldham BW, Cecere FA. guest editors, The New Normal *Military Medicine*, 2016 Feb;181(S2):1-24.

Oldham BW, Cecere FA. The New Normal of Military Orthopaedic and Rehabilitative Care. Editorial.

*Military Medicine* 2016 Nov;181(S4):1.

Resnik L, Borgia M, Silver B, Cancio J. Systematic Review of Measures of Impairment and Activity Limitation for Persons With Upper Limb Trauma and Amputation. *Archives of Physical Medicine and Rehabilitation*. PMID: 28209508. DOI: 10.1016/j.apmr.2017.01.015

Resnik L, Borgia M, Silver B. Measuring Community Integration in Persons with Limb Trauma and Amputation: A Systematic Review. *Archives of Physical Medicine and Rehabilitation*. <http://dx.doi.org/10.1016/j.apmr.2016.08.463> PMID: 27612941

Salinas MM, Wilken JM & Dingwell JB. Gait & Posture, 2017: “How humans use visual optic flow to regulate stepping during walking” <https://doi.org/10.1016/j.gaitpost.2017.05.002>

Sheehan RC, Rabago CA, Rylander JH, Dingwell JB, Wilken, JM. Use of Perturbation-Based Gait Training in a Virtual Environment to Address Mediolateral Instability in an Individual With Unilateral Transfemoral Amputation *Physical Therapy* 2016 Dec;96(12):1896-1904. Epub 2016 Jun 8. PMCID: PMC5131184.

Stanhope SJ, Wilken JM, Pruziner AL, Dearth CL, Wyatt M, Ziemke GW, Strickland R, Milbourne SA, Kaufman KR. The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium: Reaching in Partnership for Optimal Orthopaedic Rehabilitation Outcomes. *Military Medicine* 2016 Nov;181(S4):13-19.

#### **In Revision**

Hsieh, K.L., Sheehan, R.C., Wilken, J.M., and Dingwell, J.B. (In Revision) “Healthy Individuals are More Maneuverable When Walking Slower While Navigating a Virtual Obstacle Course” *Gait & Posture*.

#### **In Preparation**

Sheehan, R.C., Ruble, M.D., Dingwell, J.B., and Wilken, J.M. (In Preparation) “Individuals with Lower Limb Trauma Prioritize Stability over Maneuverability When Navigating a Virtual Obstacle Course” To submit to *Gait & Posture*.

Dingwell, J.B., and Cusumano, J.P. (In Preparation) “Strategies for Controlling Lateral Stepping Movements in Human Walking” To submit to *PLoS Computational Biology*.

Rylander, J.H., Cusumano, J.P., Wilken, J.M., and Dingwell, J.B. (In Preparation) “Frontal Plane Step-To-Step Control Strategies in Persons With Transtibial Amputation” To submit to *Journal of Biomechanics*

Koehler-Nicholas, S.R., Nickel, E.A., Barrons, K., Blaharski, K.E., Schnall, B.L., Hendershot, B.D., Hansen, A.H. Mechanical Characterization of Prosthetic Feet for Weighted Walking. In preparation for submission to *Journal of Biomechanics*

#### **Abstracts/Presentations/Invited Talks:**



Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 19 February 2014

Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 20 February 2015

Wingate AF, Kisala PA, Pruziner AL, Dearth CL, Tulskey DS. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. *Military Health System Research Symposium*. 17-20 August 2015, Ft. Lauderdale, FL

ON, Beck, AM Grabowski. Characterizing the Stiffness of Running-Specific Prostheses. *American Orthotic & Prosthetic Association, Boston, MA, 2016*.

ON, Beck, P Taboga, AM Grabowski. Characterizing the Stiffness of Lower-Limb Running-Specific Prostheses. *American Society of Biomechanics Annual Meeting, Raleigh, NC, 2016*.

ON, Beck, P Taboga, AM Grabowski. Asymmetric Forces Increase the Metabolic Cost of Running for Individuals with a Unilateral Leg Amputation. *American Society of Biomechanics Annual Meeting, OH, 2015*.

ON, Beck, P Taboga, & AM Grabowski. Lower Prosthetic Stiffness Minimizes the Metabolic Cost of Running for Individuals with Bilateral Leg Amputations. *American Society of Biomechanics Annual Meeting, OH, 2015*.

ON, Beck, P Taboga, & AM Grabowski. Asymmetric Forces Increase the Metabolic Cost of Running for Individuals with a Unilateral Leg Amputation. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015*.

ON, Beck, P Taboga, & AM Grabowski. Lower Prosthetic Stiffness Minimizes the Metabolic Cost of Running for Individuals with Bilateral Leg Amputations. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015*.

ON Beck & AM Grabowski. 2017 *Military Health System Research Symposium*. Kissimmee, FL. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

ON Beck, P Taboga, & AM Grabowski. *Rocky Mountain American Society of Biomechanics 2017*. Estes Park, CO. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

ON Beck & AM Grabowski. *American College of Sports Medicine 2017*. Denver, CO. Is the metabolic cost of running different for athletes with unilateral versus bilateral transtibial amputations?

ON Beck, P Taboga, & AM Grabowski. *American Society of Biomechanics 2017*. Boulder, CO. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

P Taboga, ON Beck, & AM Grabowski. *American Society of Biomechanics 2017*. Boulder, CO. Top sprinting speed is influenced by prosthetic model, but not stiffness or height, for athletes with bilateral transtibial amputations.

JP Cusumano, & JB Dingwell (2013) "On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics," *Proceedings of the 2013 Dynamic Walking Meeting*, Pittsburgh, PA, June 10-13, 2013.

JB Dingwell\*, JP Cusumano, JH Rylander, & JM Wilken (Submitted) "How Humans Regulate Lateral Stepping Movements and Balance While Walking," **2016 Biomechanics and Neural Control of Movement Conference**, Mt. Sterling, OH, June 12-16, 2016.

JB Dingwell\*, JP Cusumano, JH Rylander, & JM Wilken (2016) "Frontal Plane Stepping Control and Lateral Balance in Human Walking," **40th Annual Meeting of the American Society of Biomechanics**, Raleigh, NC, Aug. 2-5, 2016.

JB Dingwell & JP Cusumano. (2013) "Using Perceptual Cues to Regulate Walking From Strideto-Stride," **Proceedings of the 43rd Annual Meeting of the Society for Neuroscience**, San Diego, CA, November 9-13, 2013.

JB Dingwell & JM Wilken. (Submitted) "Integrating Virtual Reality and Motion Capture for Clinical Assessment and Rehabilitation," *Invited Symposium Presentation*, **Proceedings of the 7th World Congress of Biomechanics**, Boston, MA, July 6-11, 2014.

JB Dingwell\*, JH Rylander, JP Cusumano, & JM Wilken (2015) "Control Models of Lateral Stepping in Human Walking," **Proceedings of the 2015 Dynamic Walking Meeting**, Columbus, OH, July 20-24, 2015. (Podium Presentation).

PR Golyski, BL Schnall, AH Hansen, SR Koehler-McNicholas, CL Dearth & BD Hendershot. Biomechanical Outcomes of Prosthetic Foot Stiffness During Weighted Walking. Abstract accepted as poster presentation to 41st Annual Meeting of the American Society of Biomechanics

PR Golyski, BL Schnall, AH Hansen, SR Koehler-McNicholas, CL Dearth & BD Hendershot. Biomechanical Implications of Prosthetic Foot Stiffness for Walking with Added Load. Abstract accepted as poster presentation to Military Health System Research Symposium.

PR Golyski, BL Schnall & BD Hendershot. Biomechanical Implications of Prosthetic Foot Stiffness For Loaded Walking. Poster submitted to **Walter Reed National Military Medical Center 9th Annual National Capital Region Research Competition**

Grabowski: **European College of Sport Science congress 2018**. Invited to speak (1 of 3 speakers) for a symposium, "Do prosthetic legs enhance or hinder running performance?" Dublin, Ireland.

Grabowski: **International Conference on Intelligent Robots and Systems** Invited to speak (1 of 8 speakers) for a symposium, "On the Energy Economy of Robotic and Biological Systems" The biomechanical and metabolic effects of using of powered and compliant leg prostheses on performance during human locomotion. Vancouver, British Columbia, Canada.

Grabowski: **American Orthotic & Prosthetic Association 2017**. Invited to speak (1 of 8 speakers) for a symposium, "Power in Prosthetics" Las Vegas, NV.

Grabowski: **NCAA Track and Field Rules Committee 2017**. The effects of using running specific leg prostheses on the performance of athletes with transtibial amputations. Indianapolis, IN.

Grabowski: **Human Movement Variability Conference 2017**. Effects of Leg Prostheses on Running, Sprinting, and Jumping Omaha, NE.

Grabowski: **CU Athletics Department Sports Governance Center 2017**. Does the use of a leg prosthesis provide an *advantage* or *disadvantage* to Paralympic athletes? Boulder, CO.

Grabowski: **Boulder Valley School District Arapahoe Campus 2017**. Do leg prostheses provide an advantage or disadvantage for running, sprinting, & jumping? Boulder, CO.

Grabowski: **American Academy of Orthotists and Prosthetists Annual Meeting 2017**. How do leg prostheses effect the running, sprinting & long jump performance of Paralympic athletes? Chicago, IL.

Grabowski: **USOC Paralympic Ambulatory Sprints and Jumps Coaches Summit 2017**. Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? Colorado Springs, CO.

Grabowski: **Department of Veterans Affairs Eastern Colorado Healthcare System Jewell Clinic Amputee Team Meeting 2017**. The effects of leg prostheses during walking, running, and sprinting. Denver, CO.

Grabowski: **CU Athletics Department Sports Governance Center 2016**. Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? Boulder, CO.

Grabowski: **University of Colorado Boulder Integrative Physiology Department Colloquium 2016**. Effects of leg prostheses on walking, running, sprinting, & jumping. Boulder, CO.

Grabowski: **Keynote at CU Boulder Research Administrators Breakfast 2016**. Do leg prostheses augment walking, running, sprinting or jumping? Boulder, CO.

Grabowski: **International Press Conference - Markus Rehm about to jump to Rio 2016**. Biomechanical comparison of the long jump of athletes with and without a below the knee amputation. Cologne, Germany. 1 of 3 researchers and the only US researcher invited to contribute.

Grabowski: **Northern Arizona University Biology Department Seminar 2016**. Can leg prostheses augment walking & running performance? [https://twitter.com/cbi\\_nau/status/702989123976495106](https://twitter.com/cbi_nau/status/702989123976495106) Flagstaff, AZ.

Grabowski: **International Research Forum on Biomechanics of Running-Specific Prostheses 2016**. Effects of running-specific leg prostheses on performance. Tokyo, Japan. 1 of 3 researchers invited from the US.

Grabowski: **Naval Medical Center San Diego 2015**. Can leg prostheses restore function during running and/or sprinting? San Diego, CA

Grabowski: **University of Colorado Boulder Integrative Physiology Department Colloquium 2015**. The effects of using leg prostheses during walking & running – Can we augment performance? Boulder, CO.

Grabowski: **American Society of Biomechanics Symposium 2015**. Wearable active and passive leg prostheses; Can we augment performance in people with an amputation? Columbus, OH.

LD Guinn, KZ Takahashi, AR Razzook, ES Schrank & SJ Stanhope. A proposed method for PD- AFO stiffness prescription procedure. **(Proceedings) Center for Biomedical Engineering Research Symposium**, University of Delaware, 2011.

LD Guinn, KZ Takahashi, AR Razzook, ES Schrank & SJ Stanhope. Ankle Pseudo-Stiffness is Greatest During Gait Initiation. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

EM Husson, EJ Wolf, AF Wingate, IS Davis & AL Pruziner. A Case Report on the Effect of Real Time Biofeedback Training During Running in a Servicemember with a Unilateral Transtibial Amputation. Accepted for poster presentation at Military Health System Research Symposium, August 2015.

NS Khattri, JJ Tierney, S Yarlagadda, N Shevchenko, JW Gillespie, ES Schrank & SJ Stanhope Carbon fiber based custom orthoses for augmenting net ankle moment in gait. (Proceedings) **Society for the Advancement of Material and Process Engineering**, 2013.

E Nickel, S Morin, G Voss, S Koehler-McNicholas & A Hansen. Impact test for Prosthetic Feet. Abstract accepted as podium presentation to 2017 O&P World Congress.

E Nickel, S Morin, G Voss, S Koehler-McNicholas & A Hansen. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Abstract accepted as poster to Military Health System Research Symposium.

AR Razzook, KZ Takahashi, LD Guinn, ES Schrank & SJ Stanhope. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

AR Razzook, C Gleason, R Willy, R Fellin, IS Davis & SJ Stanhope. Average Ankle Dynamic Joint Stiffness During Heel Strike Running. **(Proceedings) American Society of Biomechanics**, 2012

H Rice, ST Jamison, AL Pruziner, & IS Davis. Gait retraining to improve stance time asymmetry reduces knee external adduction moments: a case study of a unilateral transtibial amputee. Accepted as a thematic poster for presentation at the American Society of Biomechanics Annual Meeting, Columbus, Ohio, August 2015.

H Rice, ST Jamison, AL Pruziner, & IS Davis. Gait-retraining to improve stance time asymmetry reduces knee external adduction moments: a case study of an individual with a unilateral transtibial amputation. Accepted for poster presentation at Military Health System Research Symposium, August 2015.

JH Rylander\*, JP Cusumano, JM Wilken, & JB Dingwell (2015) "Frontal Plane Stepping Control in Persons with Transtibial Amputation," **Proceedings of the 39th Annual Meeting of the American Society of Biomechanics**, Columbus, OH, Aug. 5-8, 2015. (Accepted).

JH Rylander, JP Cusumano, JM Wilken, & JB Dingwell (2013) "Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation," **Proceedings of the 43rd Annual Meeting of the Society for Neuroscience**, San Diego, CA, November 9-13, 2013.

JH Rylander, JM Wilken, JP Cusumano & JB Dingwell. (2014) "Strategies for controlling lateral stepping movements in human walking," **Proceedings of the 2014 Society for Neuroscience Annual Meeting**, Washington, DC, Nov. 15-19, 2014.

JH Rylander, EJ Beltran, JM Wilken & JB Dingwell. (2014) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," **Proceedings of the 60th Annual Meeting of the Orthopaedic Research Society**, New Orleans, LA, March 15-18, 2014.

JH Rylander, JM Wilken, JP Cusumano & JB Dingwell. (Submitted) "Able Bodied Persons and Individuals with Transtibial Amputation Employ Similar Control Strategies in the Frontal Plane during Treadmill Walking," ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

MM Salinas & JB Dingwell (2014) "How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking," ***Proceedings of the 7th World Congress of Biomechanics***, Boston, MA, July 6-11, 2014.

MM Salinas\* & JB Dingwell (2016) "Balancing Competing Task Goals During Treadmill Walking," ***2016 Gait & Clinical Movement Analysis Society Annual Meeting***, Memphis, TN, May 17-20, 2016.

MM Salinas\* & Dingwell (2016) "Goal-Relevant Correction of Conflicting Goals During Treadmill Walking," ***40th Annual Meeting of the American Society of Biomechanics***, Raleigh, NC, Aug. 2-5, 2016.

MM Salinas\*, JM Wilken & JB Dingwell (2015) "How Humans Use Visual Optic Flow to Regulate Stepping Movements," ***Proceedings of the 39th Annual Meeting of the American Society of Biomechanics***, Columbus, OH, Aug. 5-8, 2015. (Accepted).

C Samaan, J Schwartz, E Graf, IS Davis & MJ Rainbow. (2013) "A Standing Alignment System Improves Between-Session Repeatability in gait Kinematics: A Preliminary Study," ***Proceedings of the Annual Meeting of the American Society of Biomechanics***, Omaha, NE, September 4-7, 2013

ES Schrank, JS Higginson & SJ Stanhope. Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. (***Proceedings***) ***American Society of Biomechanics***, 2011

ES Schrank, JS Higginson & SJ Stanhope. A Repeatable and Predictable method to Rapidly Manufacture Function-Customized Passive-Dynamic Ankle Foot Orthoses. ***Proceedings of the ASME***, 2012

RC Sheehan\*, JH Rylander, JM Wilken, & JB Dingwell (2015) "Lower Limb Trauma Impairs Lateral Walking Transitions in a Virtual Obstacle Course," ***Proceedings of the 39th Annual Meeting of the American Society of Biomechanics***, Columbus, OH, Aug. 5-8, 2015. (Accepted).

RC Sheehan\*, JM Wilken, & JB Dingwell (2016) "Perturbation Based Gait Training May Improve the Tradeoff of Stability and Maneuverability in Patients with Lower Limb Injury," ***XXIth Congress of the International Society of Electrophysiology and Kinesiology***, Chicago, IL, July 5-8, 2016.

RC Sheehan\*, JH Rylander, JM Wilken, & JB Dingwell (2015) "A Virtual Reality Rehabilitation Program Improves Mediolateral Stability in a Patient with Unilateral Transfemoral Amputation," ***Proceedings of the 2015 American Orthotic & Prosthetic Association National Assembly***, San Antonio, TX, Oct. 7-10, 2015. (Accepted - Podium).

RC Sheehan\*, JH Rylander, JM Wilken, & JB Dingwell (Submitted) "Lower Limb Trauma Alters the Priority of Stability and Maneuverability While Navigating a Virtual Obstacle Course," ***2016 Gait & Clinical Movement Analysis Society Annual Meeting***, Memphis, TN, May 17-20, 2016.

RC Sheehan, JH Rylander, JM Wilken & JB Dingwell. (2014) "A virtual reality obstacle course to improve lateral balance control in lower limb trauma patients," ***Proceedings of the 2014 Society for Neuroscience Annual Meeting***, Washington, DC, Nov. 15-19, 2014.

RC Sheehan\*, JH Rylander, JM Wilken & JB Dingwell (2016) "Lower Limb Trauma Alters the Priority of Stability and Maneuverability While Navigating a Virtual Obstacle Course," **2016 Gait & Clinical Movement Analysis Society Annual Meeting**, Memphis, TN, May 17-20, 2016.

P Taboga, ON Beck & AM Grabowski. Optimal Running Prostheses for Sprinters with Unilateral Leg Amputations. *American Society of Biomechanics Annual Meeting, OH, 2015.*

P Taboga, ON Beck & AM Grabowski. AM. Optimal Running Prostheses for Sprinters with Bilateral Leg Amputations. *American Society of Biomechanics Annual Meeting, OH, 2015.*

P Taboga, ON Beck & AM Grabowski. Optimal Running Prostheses for Sprinters with Unilateral Leg Amputations. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.*

P Taboga, ON Beck & AM Grabowski. Optimal Running Prostheses for Sprinters with Bilateral Leg Amputations. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.*

KZ Takahashi, K Sharp, P Taboga, M Wyatt, & AM Grabowski. *International Research Forum on Biomechanics of Running-Specific Prostheses* 2016. Tokyo, Japan. Energy storage and return of running specific prostheses

KZ Takahashi & SJ Stanhope. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. **(Proceedings) American Society of Biomechanics**, 2012

KZ Takahashi, SJ Stanhope & AM Grabowski. *International Research Forum on Biomechanics of Running-Specific Prostheses* 2017. Tokyo, Japan. Locomotion on springs: from biological limbs to prosthetic devices

KZ Takahashi, AR Razzook, LD Guinn, ES Schrank, TM Kepple & SJ Stanhope. Unified Deformable Segment Model of the Combined Ankle-Foot System that Does Work. **(Proceedings) American Society of Biomechanics**, 2011

KZ Takahashi, AR Razzook, LD Guinn, ES Schrank & SJ Stanhope. A Model of Normal Gait Roll-Over Dynamics One Step Closer to Customizing Prosthetic Ankle-Foot Components. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.

Tyner: "Psychosocial Challenges Affecting Patients with Major Limb Trauma," presented by Tyner, C

Tyner at the Rehabilitation Psychology Conference, February 18, 2017 (Albuquerque, NM).

Tulsky: "Development of the BADER Toolbox for measuring major extremity trauma outcomes in a military service member population" has been accepted as a poster presentation at MHSRS, to be presented August 28, 2017.

Tulsky: "BADER Toolbox Overview," presented by D. Tulsky to EACE, San Antonio, TX, May 17, 2016

Tulsky: "Selection of Common Assessment Instruments and Data Elements for Individuals with Major Extremity Trauma and/or Amputation," presented by M. Cohen and D. Tulsky at the **Military Health System Research Symposium (MHSRS)**, August 18, 2016 (Kissimmee, FL).

### **Patents:**

None at this time

### **BADER Supported and Related Projects**

#### **Publications:**

- Mazzone: Limb Salvage Versus Transtibial Amputation: A comparison of Functional Gait Outcomes. *Journal of Orthopaedic Trauma*. Manuscript In Press.
- Mazzone: Knee Osteoarthritis Prevalence and Risk Factors Associated with Traumatic Unilateral Lower Limb Amputations: A Narrative Review. *Military Medicine*. Manuscript In Press.
- Mazzone: Comprehensive Treatment Strategy for Chronic Low Back Pain in a Patient with Bilateral Transfemoral Amputations Integrating Changes in Prosthetic Socket Design. *Journal of Prosthetics and Orthotics*. Manuscript In Review.
- Takahashi KZ, Kepple TM, Stanhope SJ. A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait. *Journal of Biomechanics* 2012;45:2662-2667. PMID:22939292
- Schrank E and Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development* 2011;48(1):31-42. PMID:21328161
- Schrank ES, Stanhope SJ. Orthotic Device Research. In *Full Stride: The Past, Present, and Future of Lower Extremity Gait Systems*. Springer Publishing. *in preparation*.

#### **Abstracts and Presentations:**

- Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Quality of Life, Spatiotemporal Gait Parameters and Overall Outcomes in Patients with Elective Delayed Amputation after Failed Limb Preservation. Accepted for podium presentation. *Society of Military Orthopaedic Surgeons Annual Meeting (SOMOS) 2016*. December 2016.
- Quacinella M, Mazzone B, Wyatt M, Kuhn K. Spatiotemporal Gait Improvements After Pilon Fracture Using The Intrepid Dynamic Skeletal Orthosis. Accepted for podium presentation. *SOMOS 2016*. December 2016.
- Mazzone B, Schmitz K, Eskridge S, Shannon K, Hill O, Moore J, Farrokhi S. Physical Therapy Practice Patterns of the Military Amputee Patient. Accepted for platform presentation at *APTA Combined Section Meeting 2017*. February 2017.

- Mazzone B, Eskridge S, Shannon K, Hill O, Moore J, Farrokhi S. Early Physical Therapy Utilization Patterns and Incidence of Secondary Musculoskeletal Conditions after Lower Limb Amputation. Accepted for platform presentation at *APTA Combined Section Meeting 2017*. February 2017.
- Mazzone B, DePratti A, Farrokhi S, Wyatt M. Improved High-Level Performance with the IDEO after Return to Run Clinical Pathway.  
Platform presentation. *Military Health System Research Symposium*, Kissimmee, FL. August 2016.  
Poster presentation. *APTA Combined Section Meeting*, Anaheim, CA. February 2016.
- Mazzone B, Farrokhi S, Eskridge S, Shannon K, Hill O. Timing of lower limb amputation after trauma and its association with manifestation of secondary musculoskeletal conditions. Platform presentation. *Military Health System Research Symposium*, Kissimmee, FL August 2016.
- Yoder A, Mazzone B, Farrokhi S, Wyatt M. Changes in Intersegmental Knee Joint Forces During Walking Before and After Delayed Transtibial Amputation. Poster presentation. *Military Health System Research Symposium*, Kissimmee, FL August 2016.
- Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Spatiotemporal Gait Parameters, Quality of Life and Overall Outcomes in Patients Who Have Undergone Late Amputation After Failed Limb Preservation. Poster presentation. *Military Health System Research Symposium*, Kissimmee, FL August 2016.
- Kingsbury T, Marks M, Mazzone B, and Wyatt M. Initial Effects of the IDEO on the Gait Quality of Limb Preservation Patients with Different Usage Needs.  
Poster presentation. *American Society of Biomechanics*, Raleigh, NC, August 2016.  
Poster presentation. *Military Health System Research Symposium*, Kissimmee, FL August 2016.
- Yoder A, Mazzone B, Wyatt M, Farrokhi S. Symmetry of Ground Reaction Forces Before and After Delayed Transtibial Amputation. Poster presentation. *American Society of Biomechanics*, Raleigh, NC, August 2016.
- Sheu R, Mazzone B, Zalewski B, Wyatt M. Comprehensive Treatment Strategy for Chronic Low Back Pain in a Patient with Bilateral Transfemoral Amputations Integrating Changes in Prosthetic Socket Design. *Federal Advanced Amputation Skills Training*, Long Beach, CA, July 2016.
- Mazzone B, Yoder A, Wyatt M. Temporal-spatial parameters before and after delayed transtibial amputation. *Gait and Clinical Movement Analysis Society*, Memphis, TN, May 2016.
- Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Gait Analysis, Quality of Life and Overall Outcomes in Patients Who Have Undergone Late Amputation After Failed Limb Preservation. Platform presentation. *Academic Research Competition*, April 2016.



- Benjamin Darter, PT, PhD; Erik Wolf, PhD; **Elizabeth Husson, BS, CCRC**. (2016 February). *Gait Adaptability in Persons with Traumatic Transtibial Amputation*. Platform presentation at the Combined Sections Meeting, American Physical Therapy Association. Anaheim, CA.
- **Elizabeth M. Husson BS, CCRC**, Brad D. Hendershot, PhD, **Amanda F. Wingate, BA**, **Irene S. Davis PT, PhD**, Alison L. Pruziner, PT, DPT. (2016 May). *The Effectiveness of Real-time Biofeedback Retraining in Reducing Vertical Impact Peaks During Running in a Servicemember with Unilateral Transtibial Limb Loss*. Oral poster session presented at the 8th Annual National Capital Region Research Competition. Bethesda, MD. **\*Finalist in the case report category\***
- Wolf EJ, Darter BJ, **Saha D**. Ankle Kinematics of Service Members With and Without Transtibial Amputation while Walking on a Split Belt Treadmill. Presented at American Society of Biomechanics, Columbus, OH, from August 5-8, 2015.
- **Elizabeth M. Husson BS, CCRC**, Erik J. Wolf, PhD, **Irene S. Davis PT, PhD**, Alison L. Pruziner, PT, DPT. (2015 August). *A Case Report on the Effect of Real Time Biofeedback Training During Running in a Servicemember with a Unilateral Transtibial Amputation*. Poster session presented at the Military Health System Research Symposium. Fort Lauderdale, FL.
- **Wingate AF**, Kisala PA, Pruziner AL, Dearth CL, Tulskey DS. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. Military Health System Research Symposium, August 2015.
- Weiser S, Campello M, Lis A, **Ziemke G, Hiebert R, Faulkner, DC**, Brennan, T, Iveson B, “Feasibility of Training Physical Therapists to Implement a Psychologically-based Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries”. Poster Session presented at Military Health System Research Symposium, Kissimmee, FL, August 2016
- **Ziemke G.**, Campello M., **Hiebert R.**, Schechter-Weiner S., Rennix C., Nordin M. (August 2015) Does a coordinated, multidisciplinary Spine Team limit medical attrition related to work disabling spine conditions in the US Navy? Poster session presented at the Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL. August 2015.
- Thesing N, Kingsbury T, Myers G, Wyatt M. Comparison of Functional Outcome Measures between Patients with Knee Disarticulation and Trans-Femoral Amputations Due to Trauma. Poster at American Society of Biomechanics. September 2013.
- Kingsbury T, Marks M, Thesing N, Myers G, Isken M, Wyatt M. Use of an Amputee Gait Score to Assess Rehabilitation Progress. Podium at American Society of Biomechanics. September 2013.

- Wyatt M, Unfried B, Sessoms P, Myers G, Grabiner M, Kaufman K. Does Novel Fall-Prevention Program Improve Gait Parameters in Unilateral Transtibial Amputees?
- Podium presentation, Gait and Clinical Movement Analysis Society (GCMAS) Annual Conference, Cincinnati, Ohio May 2013.
- Kingsbury T, Yoder A, Wyatt M. Reliability of Temporal-Spatial Gait Data Across Multiple Laboratories. Poster at Gait and Clinical Movement Analysis Society. March 2015.
- Kingsbury T, Marks M, Mazzone B, Wyatt M. Initial Effects of the IDEO on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at American Society of Biomechanics. August 2016.
- Djafar T, Sharp K, Kingsbury T, Collins JD, Wyatt M. The Effect of Digital Filtering Procedures on Total Power Below the Knee during Overground Running. Poster at American Society of Biomechanics. August 2016.
- Mazzone B, Yoder A, Wyatt M. Temporal-Spatial Parameters before and after a Delayed Transtibial Amputation. Poster at Gait and Clinical Movement Analysis Society. May 2016.
- Kingsbury T, Marks M, Mazzone B, Yoder A, Wyatt M. Initial Effects of the IDEO Brace on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at Gait and Clinical Movement Analysis Society. May 2016.
- Kingsbury T, Marks M, Mazzone B, Wyatt M. Initial Effects of the IDEO on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at Military Health System Research Symposium. August 2016.
- Mazzone B, DePratti A, Farrokhi S, Wyatt M. Improved High-Level Performance with the IDEO after Return to Run Clinical Pathway. Podium at Military Health System Research Symposium. August 2016.
- Mazzone B, Farrokhi S, Eskridge S, Shannon K, Hill O. Timing of Lower Limb Amputation after Trauma and its Association with Secondary Musculoskeletal Conditions. Podium at Military Health System Research Symposium. August 2016.
- Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Spatiotemporal Gait Parameters, Quality of Life and Overall Outcomes in Patients who have Undergone Delayed Amputation after Failed Limb Preservation. Poster at Military Health System Research Symposium. August 2016.
- Yoder A, Mazzone B, Farrokhi S, Wyatt M. Intersegmental Knee Joint Forces During Walking Before and After Delayed Transtibial Amputation. Poster at Military Health System Research Symposium. August 2016.

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- Takahashi KZ, Stanhope SJ. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. **(Proceedings) American Society of Biomechanics**, 2012
- Schrank ES, Higginson JS, Stanhope SJ. Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. **(Proceedings) American Society of Biomechanics**, 2011
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- Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. A proposed method for PD- AFO stiffness prescription procedure. **(Proceedings) Center for Biomedical Engineering Research Symposium**, University of Delaware, 2011.
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- Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, Stanhope SJ. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription. **(Proceedings) Gait and Clinical Movement Analysis Society Conference**, 2011.
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**Informatics such as databases and animal models:**

- The Consortium, through the Clinical Research Core, has executed a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development and now offers the Consortium a secure and dedicated instance of the NIH Clinical Trials Database.

**Employment or research opportunities applied for and/or received based on experience/training supported by this award:**

- John Collins, a biomechanist in the gait analysis laboratory at NMCSD, currently holds a BS in Bioengineering from UC San Diego and a MA in Kinesiology with an emphasis in Biomechanics from San Diego State. He has completed his first year of studies in the University of Delaware Biomechanics and Movement Science program and returned to NMCSD in January 2016 to work on his research project. He anticipates completion of degree requirements in May 2018. However, his BADER funding will be depleted by September 30, 2017.
- Clinical Research Core staff have all found positions outside of BADER (due to funding being depleted) that were greatly facilitated by the opportunities supported by this award including research experiences, conference support and University of Delaware degree-granting and certificate programs.

## **Conclusion**

## Administrative Overview:

BADER continues progress in the following areas:

MTF and research initiative team building: Regular monthly meeting of MTF and BADER personnel will continue and focus on engagement and sustainability efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting.

### Sustainability:

At the request of a MTF representative, BADER leadership is actively working to implement a policy allowing non-University personnel to be Principal Investigators on research projects submitted through UD. As part of this policy, the University would return a portion of the F&A recovered back to the program. This contribution of F&A back into the research would make the UD F&A profile similar to that of Henry Jackson and Geneva Foundations.

Furthermore, at the request of a Consortium member, the University of Delaware has established an account to receive charitable donations directed to support and conduct specific research projects. This fund will not carry indirect costs, making it highly attractive to individual donors wishing to fund research.

### Proposal submission:

The central focus of the sustainability effort will be the submission of new proposals for additional funding.

MTF Centric Coordination and Management: For the duration of the BADER award, we will be flexing toward a new committee structure that is more MTF centric. Over the next several quarters, working toward sustainability efforts, we will continue to engage BADER Consortium Affiliates into forming large research teams to compete for large scale, impactful clinical studies. BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of the Consortium.

### Collaborations with other Consortia/Initiatives:

Leaders of the BADER Consortium have been working diligently to establish strong collaborations with other Department of Defense, VA and NIH initiatives. By collaborating with these initiatives, the BADER Consortium believes it can create extraordinary research infrastructures across the DoD and VA.

EACE: Leadership from BADER met with EACE leadership and MTF representatives at Ft. Sam Houston on June 22, 2016 to discuss transition of key BADER components to EACE or specific MTFs. Materials were prepared outlining all of the resources that BADER provides to the MTFs and other affiliated researchers. We are currently awaiting decisions from EACE leadership and MTF representatives on which components they would like to assume.

Veteran's Affairs (VA): BADER leadership continues to engage the VA. A strong partnership with the VA will be essential for sustainability efforts of the Consortium.

National Institutes of Health (NIH): The Consortium has identified a new exciting opportunity to expand our relationship with the NIH by entering a Collaboration Agreement to use the BRICS PDMS. Similar to the NIH CTDB, the BRICS system is more robust and will better suit the needs of the Consortium. As the CTDB and BRICS are on the same general platform, the learning curve for staff will not be as steep as would be for a new program. This is a great advancement for the IT infrastructure of the Consortium.

The Consortium is currently working under a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This Collaboration Agreement was renewed for an additional two years in December 2014 – and currently remains active. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development.

Post baccalaureate training: John David Collins (NMCSO) continues to progress toward his PhD in Biomechanics and Movement Sciences at the University of Delaware and returned to NMCSO in January 2016 to continue his research to complete his degree requirements. Mr. Collins anticipates completion of degree requirements by August 2017. Several MTF staff expressed interest in the Masters and PhD programs, however, with the decision not to continue funding for the BADER Consortium beyond September 2017, these enrollments were declined.

### **Conclusion**

As we complete year 6 (first no cost extension) period of performance, efforts continue to be focused on the “Engagement” and “Sustainability” phases. BADER is actively working on the successful accomplishment of tasks as outlined in the proposed statement of work with the primary focus being the completion of the remaining research projects.

As we continue to focus on sustainability efforts, BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of Consortium activities. The significant change in personnel at MTF sites will require substantial training and research program facilitation.

Regular monthly meeting of MTF and BADER personnel will continue and focus on engagement and sustainability efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting.

Over the next two years, working toward sustainability efforts, we will continue to engage BADER Consortium Affiliates into forming large research teams to compete for large scale, impactful clinical grants.

We look forward to continuing our work in strengthening orthopaedic rehabilitation research to bring all Wounded Warriors back to optimal function.



## **APPENDICES**

## **APPENDIX A: Affiliations**

### ***Affiliations:***

#### Government partners:

- CDMRP
- Brooke Army Medical Center
- Naval Medical Center Portsmouth
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- National Institutes of Health
- Department of Veterans Affairs
- Denver Rehabilitation Institute
- ECBC/ADM

#### Academic partners:

- University of Delaware
- Spaulding Rehabilitation Hospital
- Mayo Clinic
- University of Texas Austin
- University of Colorado
- University of Michigan
- New York University
- Christiana Care Health System
- Vanderbilt University
- University of Iowa
- Simbex, LLC

#### Industry partners:

- C-Motion, Inc
- Independence Prosthetics and Orthotics
- BiOM
- Ossur
- Otto-Bock
- Hanger Orthopedics

#### Non-Profit partners:

- Amputee Coalition
- Agrability

## APPENDIX B: BADER Consortium Affiliates

<b>Aldridge, Jennifer</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Archer, Kristin R., PhD, PT, DPT</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Vanderbilt
<b>Bonato, Paolo, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Spaulding Rehabilitation Hospital
<b>Brown, Douglas</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Buchanan, Thomas S., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Campello, Marco, PhD</b>	BADER Consortium Affiliate	New York University
<b>Carney, Joseph</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Casler, Rick</b>	BADER Consortium Affiliate	BiOM
<b>Cella, David, PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Childs, John D., PT, PhD, MBA</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Dept. of the Army
<b>Collins, John-David</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<b>Crandell, David, MD</b>	BADER Consortium Affiliate	Spaulding Rehabilitation Hospital
<b>Dankmeyer, Charles H., CPO</b>	BADER Consortium Affiliate	Dankmeyer, Inc.
<b>Davis, Irene Sprague, PhD, PT</b>	Director, Clinical Research - BADER Consortium	Spaulding Rehabilitation Hospital
<b>Davis, Samuel, PhD</b>	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<b>de Lateur, Barbara J., MD, MS</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Johns Hopkins Medicine
<b>Dingwell, Jonathan B., PhD</b>	BADER Consortium Affiliate	Pennsylvania State University

<b>Dromsky, David</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
<b>Evans, Boyd</b>	BADER Consortium Affiliate	Oak Ridge National Labs
<b>Farrell, Todd R., PhD</b>	BADER Consortium Affiliate	Liberating Technologies, Inc.
<b>Fatone, Stefania</b>	BADER Consortium Affiliate	Northwestern University
<b>Ferguson, John</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ficke, James R., PhD</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Fitzgerald, G. Kelley, PhD</b>	BADER Consortium Affiliate	Univeristy of Pittsburgh
<b>Friedman, Matthew J., MD, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Dartmouth
<b>Gard, Steven A., PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Gill, Norman "Skip" LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Gillespie, John W., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Grabowski, Alena, PhD</b>	BADER Consortium Affiliate	University of Colorado Boulder
<b>Greenwald, Rick, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Simbex
<b>Groer, Shirley, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Department of Veterans Affairs
<b>Hansen, Andrew, PhD</b>	BADER Consortium Affiliate	Department of Veterans Affairs
<b>Hendershot, Brad</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Hicks, Gregory E., PhD, PT</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Delaware

<b>Hopkins, Mark S., PT, CPO, MBA</b>	BADER Consortium Affiliate	Dankmeyer, Inc.
<b>Hsu, Joseph, PhD, LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Jarzombek, Sandi</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Kaufman, Kenton R., PhD, PE</b>	Director, Scientific Cores	Mayo Clinic
<b>Kelley, Kevin</b>	BADER Consortium Affiliate	Ottobock
<b>Kingsbury, Trevor</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
<b>Klute, Glenn K., PhD</b>	BADER Consortium Affiliate	University of Washington
<b>Kolm, Paul, PhD</b>	BADER Consortium Affiliate, Director, Biostatistics Core	Christiana Care Health Services, Inc.
<b>Kram, Rodger, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Colorado
<b>Kuiken, Todd, MD, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	Rehabilitation Institute of Chicago
<b>Pruzier, Alison</b>	MTF Representative, BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Logerstedt, David, PT, PhD, MPT, SCS</b>	BADER Consortium Affiliate	University of Delaware
<b>Ludewig, Paula M.</b>	BADER Consortium Affiliate	University of Minnesota
<b>Milbourne, Suzanne A., PhD</b>	Clinical Research Core Manager, BADER Consortium Affiliate	University of Delaware
<b>Miller, Ross H., PhD</b>	BADER Consortium Affiliate	University of Maryland
<b>Mulroy, Sara, PhD, PT</b>	BADER Consortium Affiliate	Rancho Los Amigos National Rehabilitation Center
<b>Neptune, Rick</b>	BADER Consortium Affiliate	University of Texas at Austin

<b>Nordin, Margareta</b>	BADER Consortium Affiliate	New York University
<b>Nowinski, Cindy, MD, PhD</b>	BADER Consortium Affiliate	Northwestern University
<b>Owens, Johnny, PT</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Pasquina, Paul, COL</b>	BADER Consortium Affiliate	Uniformed Services University of the Health Sciences
<b>Powers, Christopher M., PhD, PT</b>	BADER Consortium Affiliate	University of Southern California
<b>Rabago, Chris</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Resnick, Linda, PhD</b>	BADER Consortium Affiliate	Brown University
<b>Richards, James G., PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Ritland, Bradley, CAPT</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Rodriguez, Kelly</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Rosenthal, Michael D., CAPT</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
<b>Royer, Todd, PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Sacher, Richard S</b>	BADER Consortium Affiliate	University of Delaware
<b>Schaffer, Scott, LTC</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Schnall, Barri</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Scoville, Charles</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Selbie, William Scott, PhD</b>	BADER Consortium Affiliate, Director, Biomechanics Core	C-Motion, Inc.
<b>Sessoms, Pinata</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)

<b>Shim, Jae Kun, PhD</b>	BADER Consortium Affiliate	University of Maryland
<b>Silverman, Anne</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Sluka, Kathleen A., PT, PhD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Iowa Health Care
<b>Snyder-Mackler, Lynn, PT, PhD, FAPTA</b>	BADER Consortium Affiliate	University of Delaware
<b>Stanhope, Steven J., PhD</b>	Director, BADER Consortium	University of Delaware
<b>Swiontkowski, Marc F., MD</b>	BADER Consortium Affiliate, Research Advisory Committee Member	University of Minnesota
<b>Takahashi, Kota, PhD</b>	BADER Consortium Affiliate	University of Nebraska Omaha
<b>Thesing, Nancy</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCSD)
<b>Tulsky, David, PhD</b>	BADER Consortium Affiliate, Director, Outcome Measures Core	University of Delaware
<b>Vernon, Michael</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ward, Samuel R., PT, PhD</b>	BADER Consortium Affiliate	University of California, San Diego
<b>Weir, Richard, PhD</b>	BADER Consortium Affiliate	University of Colorado
<b>Wilken, Jason, PhD, MPT</b>	MTF Representative	University of Iowa
<b>Wyatt, Marilyn</b>	MTF Representative	Naval Medical Center San Diego (NMCSD)
<b>Yack, John</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)

## APPENDIX C: BADER Staff Participation in non-BADER Funded Studies

Project = active/continuing protocol

Activity = research support

	TITLE	STAFF	ROLE	Current STATUS	SITE
<b>Activity</b>	Journal club to support the application of new clinical and research data collection techniques	Collins	Lead	Leading a journal club to introduce new and emerging methodologies for data collection and analysis.	NMCSD
<b>Activity</b>	Power imbalance resolved with novel 6DOF segmental power analysis	Collins	coauthor	submitted to ISB 2017, presentation at ISB 2017, Manuscript in review at Journal of Biomechanics	NMCSD
<b>Activity</b>	Net ankle psuedo-stiffness is influenced by walking speed but not age for older adult women	Collins	First author	Manuscript submitted to Gait and Posture. Podium presentation at ASB 2017 in Foot and Ankle	NMCSD
<b>Activity</b>	Clinical Data Collection	Hulcher	Data collection	Collect, process and prepare reports for use in patient PT evaluations	NMCP
<b>Activity</b>	Physical Therapy Spine Research Department	Hiebert	Department Admin Reviewer	Oct - Dec 2016 activity: Ongoing review of de-identified information of all ongoing protocols. Implementing	NMCP



	TITLE	STAFF	ROLE	Current STATUS	SITE
				patient data storage practices, training research staff in the department on correct research practices (e.g. consenting participants, patient data file storage, regulatory binder compilation).	
<b>Activity</b>	Obstacles and Facilitators of Work Reintegration in Military Members with Deployment Related Musculoskeletal Injuries	Hiebert	Associate Investigator	Apr - June 2017: Protocol not funded by CDMRP. Now submitted as a program grant to CDMRP. LOI will be submitted July 15 2017	NMCP
<b>Activity</b>	Shore based psychologically-based physical therapy	Hiebert	Associate Investigator	Apr - Jun 2017: CDMRP not recommended for funding	NMCP
<b>Project</b>	Functional Evaluation of Patients after Limb Salvage or Transtibial Amputation	Wingate	AI	Consent, data collection, admin support	NMCSD
<b>Project</b>	Improved Training Method for Advanced Rehabilitation of Warfighters with Lower Extremity Trauma	Wingate	AI, Admin Support	Working on consent, protocol, IRB documents, admin support	NMCSD

	TITLE	STAFF	ROLE	Current STATUS	SITE
<b>Project</b>	The Naval Medical Center San Diego Gait Lab Research Registry	Wingate	AI	Consent, data collection, admin support	NMCSD
<b>Project</b>	Research support tasks	Wingate	Research Support	Assis with IRB submissions, continuing reviews, lit search, etc.	NMCSD
<b>Project</b>	RMS/EACE database	Wingate	database support, updating information, creating	ongoing	NMCSD
<b>Project</b>	Grant writing	Wingate	grant writing for staff support	grants have been submitted	NMCSD
<b>Project</b>	Retrospective: Patient-reported outcomes (data pulled from Registry)	Wingate	literature search, writing protocol, analyze data, etc.	podium presentation at MHSRS 2017 on preliminary data	NMCSD
<b>Project</b>	Establishing a data set of qualitative and quantitative gait data in control subjects using a 6DoF marker set	Wingate	AI, writing protocol, managing IRB docs	ongoing; data collection	NMCSD
<b>Project</b>	Comparing functional outcomes in low energy lisfranc injuries treated with ORIF vs. Primary Arthrodesis	Wingate	AI, writing protocol, managing IRB docs	ongoing; data collection	NMCSD

	TITLE	STAFF	ROLE	Current STATUS	SITE
<b>Project</b>	Patient-Reported Outcomes	Wingate	AI, managing software	ongoing, looking for CATs and other subjective measure software	NMCSD
<b>Project</b>	Prosthetics/Orthotics Blanket Protocol Database	Hulcher	Data management	Created an excel workbook to input responses from a survey and automatically calculate some metrics based off of injury category.	WRNMMC
<b>Project</b>	CAREN Blanket Protocol Database	Hulcher	Data management	Created an excel workbook to input responses from a survey and automatically calculate some metrics based off of injury category.	WRNMMC
<b>Project</b>	Osteointegration ROM and ADL improvement testing	Hulcher	Data collection	Working with 3 patients undergoing upper extremity osteointegration surgery. Conducted presurgery range of motion (ROM) and activities of daily living (ADL) baseline tests, ROM retests after each stage of surgery, and plan to retest everything once surgeries are	WRNMMC

	TITLE	STAFF	ROLE	Current STATUS	SITE
				complete. Using literature to determine useful outcome measures generated by the ADLs.	
<b>Project</b>	Clinical and Radiographic Outcomes Following Anterior Cervical Discectomy and Fusion Versus Anterior Cervical Discectomy and Arthroplasty in Active Duty Service Members.	Hiebert	Associate Investigator	Sent for publication	WRNMMC
<b>Project</b>	Retrospective Administrative Limited Duty Outcomes follow-up	Hiebert	Associate Investigator	Publication manuscript in progress	NMCP
<b>Project</b>	A pilot study to test the efficacy of psychologically-based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries	Hiebert	Associate Investigator	Manuscript in progress	NMCP

**APPENDIX D: Quad Charts for BADER funded research projects**

**APPENDIX E: Toolbox – Focus Group Executive Summary**

**APPENDIX F: Patient Reported Outcomes Assessment Training Manual**

**APPENDIX G: Patient Reported Outcomes Assessment Training Presentation**

**APPENDIX H: Manuscripts**

## APPENDIX D

# Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators



OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award W81XWH-11-2-0222

PI: Alison L. Pruziner Org: DoD-VA Extremity Trauma and Amputation Center of Excellence (WRNMMC) Award Amount: \$1,778,409

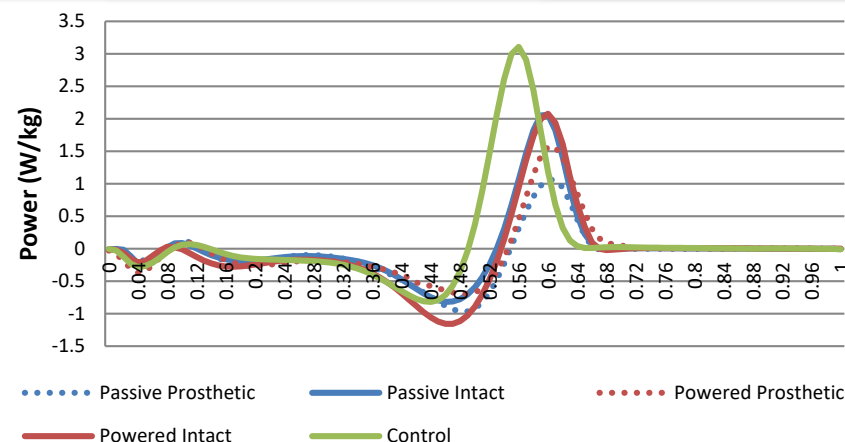
## Study/Product Aim(s)

Aim 1: Identify biomechanical, metabolic, functional, and/or subjective differences between using a passive versus a powered ankle prosthesis in individuals with unilateral transtibial limb loss, who function at a Medicare Functional Classification Level K2 and K3.

Aim 2: Identify stability of biomechanical, metabolic, functional, or subjective measures over time when wearing a powered ankle prosthesis in individuals with unilateral transtibial limb loss, who function at a Medicare Functional Classification Level K2 and K3.

## Approach

- Biomechanical, metabolic, functional, and subjective measures will be compared between a standard passive and powered ankle prosthesis
- Comparisons will be tracked over a six-month time period to evaluate stability of measures.
- It is hypothesized that outcomes will be improved with the application of a powered ankle prosthesis and that these improvements will be maintained for the study duration.



Accomplishment: Data collection and analysis ongoing. Preliminary analysis demonstrates increased power generation at push off from the powered ankle prosthesis, relative to a passive prosthesis

## Timeline and Cost

Activities FY	13	14	15	16	17	18	19
Study preparation	■						
Recruitment		■	■	■	■	■	
Data Collection			■	■	■	■	
Data Analysis					■	■	
Manuscript Preparation							■
Budget (\$K)	0	693	177	186	250*	300*	172*

\* Estimate of costs

Updated: 17 July 2017

## Goals/Milestones

**FY13-16 Goal** – Study prep and initiation

- ☒ Submission of IRB application
- ☒ Hiring of key study personnel
- ☒ Recruitment of K2 and K3 ambulators
- ☒ Initiation of data collection
- ☒ Initiate data analysis and interpretation

**FY17-18 Goal** – Data collection and analysis

- ☐ Continue recruitment, collection, and analysis

**FY19 Goal** – Dissemination

- ☐ Complete data collection and analysis
- ☐ Draft grant proposal for potential follow-on funding
- ☐ Disseminate information through presentations and publications

## Comments/Challenges/Issues/Concerns

- Goals pushed back as a result of delays in release of funding and recruitment

## Budget Expenditure to Date

Projected Expenditure: \$ 1778 K

Actual Expenditure: \$ 1251 K



# What is the optimal stiffness and height of a running-specific prosthesis?

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award

W81XWH-11-2-0222



PI: Alena Grabowski

Org: Dept. of Veterans Affairs Eastern Colorado Healthcare System

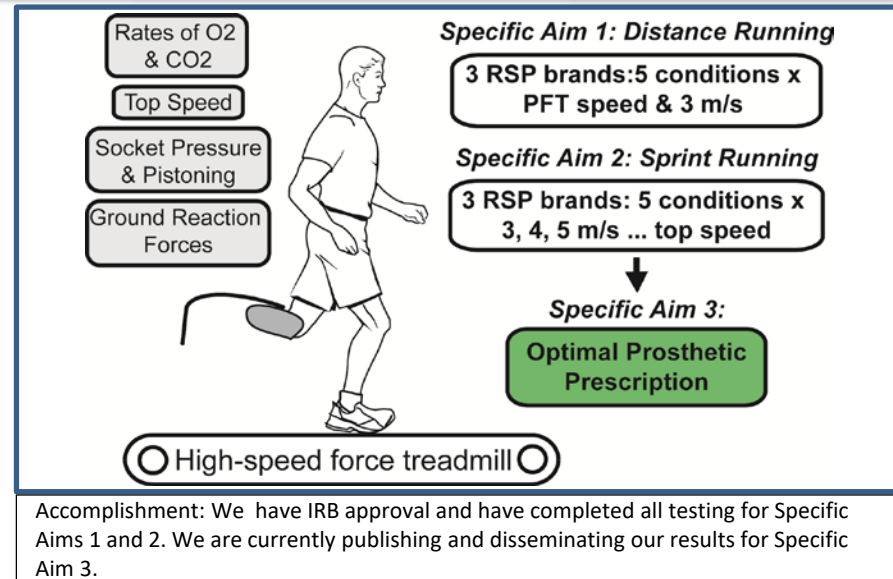
Award Amount: \$882,827

## Study/Product Aim(s)

- There are no science-based, objective methods for running-specific prosthesis (RSP) prescription. Existing practices waste time, money, resources & do not necessarily optimize prescription
- We seek to develop a method for optimal RSP prescription so that Soldiers and Veterans with transtibial amputations can regain the greatest possible level of functional ability and return to active duty if they choose.

## Approach

- Develop a science-based method for prescribing RSPs
- Measure effects of RSP stiffness & height on biomechanics, metabolic demand, & performance with: **SA1:** Distance-running RSPs, **SA2:** Sprint-running RSPs
- Combine SA 1 & 2 results to develop clinically relevant, quantitative algorithms for RSP prescription based on weight, amputation level, limb segment length, and desired running speed



## Timeline and Cost

Activities	CY	13	14	15	16	17
IRB approval and RSP stiffness testing (SA1 & 2)						
Recruit, collect & analyze data, publish results (SA1)						
Recruit, collect & analyze data, publish results (SA2)						
Develop quantitative algorithm for RSP prescription (SA3)						
<b>Estimated Budget (\$K)</b>			<b>\$337</b>	<b>\$168</b>	<b>\$240</b>	<b>\$138</b>

Updated: (10/04/2017)

## Goals/Milestones

**CY13 Goal** – IRB approval for SA1 and SA2

- ☒ Local IRB approval
- ☒ DoD IRB approval

**CY14 Goal** – Measure RSP effects during running

- ☒ Determine stiffness of RSP
- ☒ Experimentally test different stiffness & height RSPs

**CY15 Goal** – Measure RSP effects during sprinting

- ☒ Determine stiffness of RSP
- ☒ Experimentally test different stiffness & height RSPs

**CY16-17 Goal** – Develop a quantitative algorithm for RSP prescription  
☐ Use SA1 and SA2 results to develop a clinical algorithm for RSP prescription: In progress

## Comments/Challenges/Issues/Concerns

- Some budget items have not yet been billed for.

## Budget Expenditure to Date

Projected Expenditure: \$883k

Actual Expenditure: ~\$800k



# Community Reintegration, Functional Outcomes and QOL after Upper and Lower Extremity Trauma

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award  
W81XWH-11-2-0222

PI: David Tulsy, Ph.D.

Org: University of Delaware

Award Amount: \$2,059,323



## Study/Project Aim(s)

This project aims to develop a "Toolbox" of outcome measures to serve as CDEs across research studies and clinical evaluations, as follows:

1. To characterize health, physical functioning, community re-integration and emotional functioning in individuals with limb trauma and upper and lower limb amputations who receive outpatient services at MTFs and VAs.
2. To conduct a pilot study of the Toolbox and preliminarily examine the concurrent validity and reliability of the Toolbox in military and civilian samples of individuals with upper or extremity trauma/amputation.

## APPROACH

Aim 1: Literature reviews and qualitative research (i.e., focus groups with patients and clinicians) will inform selection of domains to be measured and tests and measurement scales to be included in the Toolbox, with consensus stakeholder input.

Aim 2: Toolbox measures will be administered by trained, certified examiners to a sample of individuals who have sustained upper or lower extremity trauma.

## Timeline and Cost

Activities	CY	14	15	16	17
Study Setup/IRBs		<div><div></div></div>			
Literature Reviews		<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
Focus Groups		<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	
Expert/Clinician Feedback		<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	
Qualitative Analysis			<div><div></div></div>	<div><div></div></div>	
Selection of Toolbox Measures via Consensus				<div><div></div></div>	<div><div></div></div>
Prepare Materials & Train Examiners				<div><div></div></div>	<div><div></div></div>
Pilot Test Upper Extremity Battery					<div><div></div></div>
Pilot Test Lower Extremity Battery					<div><div></div></div>
Develop Test Administration Videos					<div><div></div></div>
Data Analysis					<div><div></div></div>
Estimated Budget (\$K)		\$0	\$716	\$681	\$662



Accomplishments: Toolbox measures have been selected and pilot data collection is completed.

## Goals/Milestones

**CY14 Goal** – Study setup

- ☒ Prepare IRB protocol

**CY15 Goals** – Gather Input to inform Toolbox decisions

- ☐ Literature Review
- ☒ Focus Groups & Expert/Clinician Input
- ☒ Qualitative Analysis

**CY16 Goals** – Toolbox Measure Selection

- ☒ Consensus Meeting & Final Instrument Selection
- ☒ Prepare Materials & Train Examiners

**CY17 Goals** – Data Collection, Analysis & Video Development

- ☒ Pilot Test Upper Extremity Battery
- ☒ Pilot Test Lower Extremity Battery
- ☐ Conduct Data Analysis
- ☐ Develop Test Administration Videos

## Comments/Challenges/Issues/Concerns

- Overall timeline shifted due to late project start, but all on schedule.

## Budget Expenditure to Date

Projected Expenditure: \$2,059,323

Actual Expenditure: \$1,958,157

# Maximizing Outpatient Rehabilitation Effectiveness (MORE)

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award

W81XWH-11-2-0222



PI: Amy Bowles

Org: SAMMC

Award Amount: \$1.5M

## Study/Product Aim(s)

- AIM #1: To determine factors that predict clinical outcomes following outpatient rehabilitation in a military setting.
- AIM #2. To determine the extent to which patient reported and observed outcomes change and covary during the course of outpatient rehabilitation.
- AIM #3. To determine the magnitude of residual deficits following completion of outpatient rehabilitation.

## Approach

- Participants: Individuals who have experienced lower limb injury.
- Prospective collection of objective outcomes data throughout the course of rehabilitative care at Ft Hood, SAMMC, and the University of Iowa.
- Measures will be used to assess physical, cognitive, and psychosocial health and function every three weeks.



An improved understanding of the types and magnitudes of deficits present, and their relative contributions to treatment success, goal attainment, and health related quality of life is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness.

## Timeline and Cost

Activities	CY	14	15	16	17	18	19
Regulatory Approval, Purchasing							
Hire and Train Staff							
Enrollment and Data Collection							
Data analysis and dissemination							
Estimated Budget (\$K)		60	90	90	90		

## Goals/Milestones

**CY14-15 Goal** – Receipt of funds, Regulatory, Hiring and System tests

- ☒ IRB protocol submitted, data collection framework under development, training materials in preparation.
- ☒ Purchase study equipment, hire and train staff.

**CY16-18 Goals** – Subject Enrollment and Data Collection

- ☐ Enroll over 1,000 participants.
- ☐ Collect complete data on over 90% of participants.

**CY18-19 Goal** – Data analysis and dissemination of findings

- ☐ Complete data audit and statistical analysis.
- ☐ Presentation of results to clinical staff and manuscript submission.

## Comments/Challenges/Issues/Concerns

- Staff turnover resulted in delayed recruitment.

## Budget Expenditure to Date

Projected Expenditure: \$1.5M

Actual Expenditure: \$600K

Updated: OCT 2017

# Characterization of Prosthetic Feet for the Weighted Walking in Service Members with Lower-Limb Amputations

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award

W81XWH-11-2-0222

PI: Schnall, Barri

Org: Walter Reed National Military Medical Center

Award Amount: \$401,136

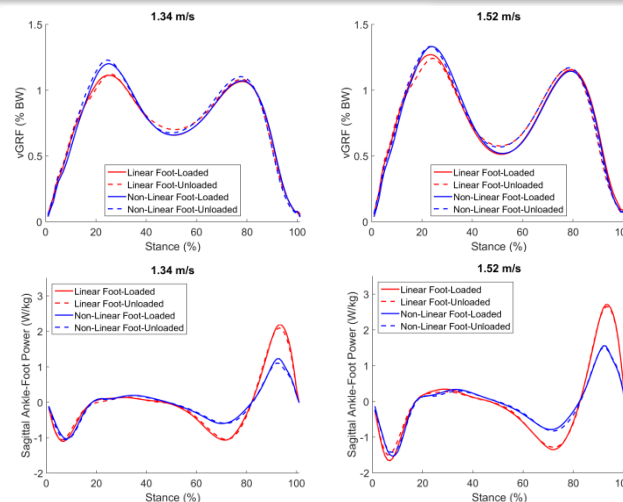


## Study/Product Aim(s)

To provide objective criteria for evaluating and prescribing prosthetic ankle-foot components for Service Members with transtibial amputations wishing to perform load carriage and other physically demanding tasks

## Approach

- Determine mechanical characteristics and durability of current prosthetic feet intended for highly functional transtibial prosthesis users
- Compare the biomechanical and functional outcomes between prosthetic feet with linear and non-linear mechanical properties during weighted walking and high-intensity activities.



Intact limb vertical ground reaction force (vGRF) and prosthetic ankle-foot power (n=13) indicate the non-linear (vs. linear) prosthetic foot was associated with larger intact limb loads and decreased prosthetic foot power generation.

## Timeline and Cost

Activities	FY	15	16
IRB Approval		<div style="width: 10px; height: 10px; background-color: #92d050; border: 1px solid black;"></div>	
Mechanical testing of feet		<div style="width: 10px; height: 10px; background-color: #92d050; border: 1px solid black;"></div>	
Collect and Process Subjects		<div style="width: 40px; height: 10px; background-color: #92d050; border: 1px solid black;"></div>	<div style="width: 5px; height: 10px; background-color: #92d050; border: 1px solid black;"></div>
Publications		<div style="width: 30px; height: 10px; background-color: #92d050; border: 1px solid black;"></div>	
Estimated Budget (\$K)		\$ 266K	\$ 134K

## Goals/Milestones

### FY15 Goals – IRB Approval

- ☒ Minneapolis VA Health Care System (MVAHCS)
- ☒ Obtain IRB approval WRNMMC
- ☒ Begin mechanical testing of feet and VA participants

### FY16 Goals – Data collection / publication

- ☒ Publish preliminary results
- ☒ Data collection at WRNMMC
- ☐ Publish final results

Updated: 11 October 2017

# Improving Step-To-Step Control of Walking in Traumatic Amputees

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award

W81XWH-11-2-0222



PI: Jonathan B. Dingwell

Org: U. Texas Austin: with BAMC / CFI

Award Amount: \$ 679,300

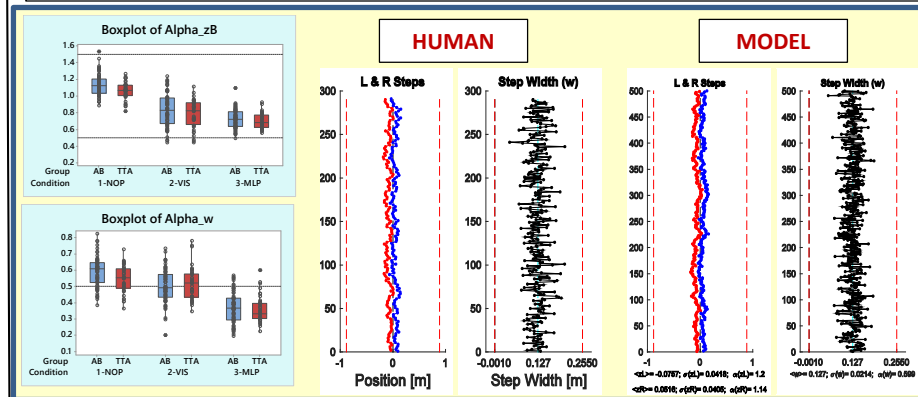
## Study/Product Aim(s)

- Patients with lower-limb amputation have a very high risk of falls
- This risk increases greatly for patients with more severe injuries
- Most falls occur during physical activities like walking
- Preventing a fall when walking requires the ability to properly control foot placement to stop yourself from falling
- This project has 2 Specific Aims:
- 1) To quantify the extent of deficits in lateral foot placement control exhibited by patients with amputation during walking
- 2) To determine the extent to which a virtual reality gait training intervention can improve walking ability in these patients

## Approach

The first study was a cross-sectional comparison of CFI patients with unilateral transtibial amputation (TTA) and able-bodied controls (AB) (see right). The second study is a prospective intervention study in CFI patients with amputation/poly-trauma.

**4 Peer-Reviewed Articles Published:** Dingwell & Cusumano, *Gait & Posture*, 2015; John, Cusumano, & Dingwell, *PLoS Comput. Biol.*, 2016; Sheehan, Rylander, Wilken, & Dingwell, *Physical Therapy*, 2016; Salinas, Wilken, & Dingwell, *Gait & Posture*, 2017



**NEW RESULTS:** LEFT: Patients (TTA) exhibited tighter control ( $\downarrow \alpha$ ) of position (zB) & step width (SW) across perturbation conditions. RIGHT: Computational models predict stepping patterns and changes in stepping patterns to reveal root causes of control.

## Timeline and Cost

Activities	CY	13	14	15	16
Aim 1: Refine / Finalize Analyses		<div></div>			
Aim 1: Analyze Data / Publish		<div></div>			
Aim 2: Collect Data		<div></div>	<div></div>		
Aim 2: Analyze Data / Publish			<div></div>		
Estimated Budget (\$K)		\$230	\$225	\$225	\$000

## Goals/Milestones

### CY13 Goals –

- ☑ Aim 1: Develop, refine, and finalize our data analysis methods.
- ☑ Aim 1: Analyze data. Identify primary deficits in patients (Figure).
- ☑ Aim 2: Finalize BAMC IRB approvals. Begin patient enrollment.

### CY14 Goals –

- ☑ Aim 1: Finalize analysis. Disseminate results.
- ☑ Aim 2: Continue patient enrollment (CFI). Begin data analyses.

### CY15 Goals –

- ☑ Aim 2: Finalize data collection / participant enrollment (CFI).
- ☑ Aim 2: Finalize data analysis. Disseminate results.

### Comments/Challenges/Issues/Concerns

- All Data Collection/Analyses Complete. Publication Efforts Ongoing.

### Budget Expenditure to Date

Projected Expenditure: \$679k

Actual Expenditure: \$679k

Updated: (July 11, 2017)

# Walk to Run Retraining (RETRAIN)

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award  
W81XWH-11-2-0222



**PI:** Insert PI Irene S. Davis

**Org:** Spaulding/Harvard

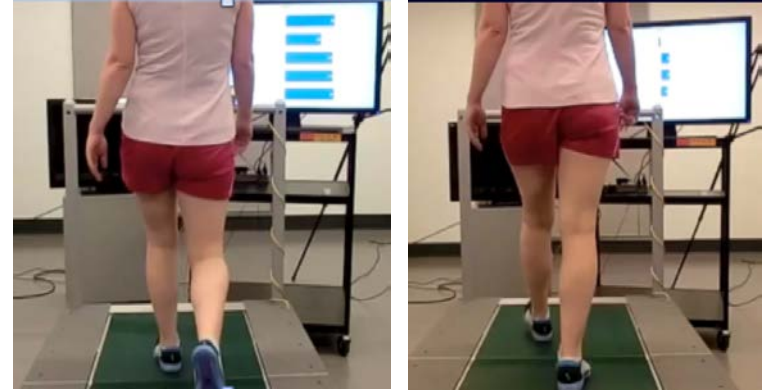
**Award Amount:** \$708,524

## Study/Product Aim(s)

- Aim 1. To determine if gait retraining using realtime kinetic feedback in individuals with unilateral, transtibial amputations alters the asymmetry of stance time during walking.
- Aim 2. To determine whether functional outcomes are altered with gait retraining.
- Aim 3. To determine the validity of an insole as a mobile monitor for assessing gait symmetry during walking running.

## Approach

Unilateral transtibial amputees with asymmetry of stance time during walking and/or vertical impact peaks during running will be recruited. They will undergo 12 walk retraining and/or 12 run retraining sessions using realtime biomechanical feedback to improve their gait. Gait and function will be reassessed post-training and at 1 month. The validity of an instrumented insole to monitor these gait parameters outside the lab will be determined.



Subject receiving realtime feedback on her symmetry of stance times during walking. The long bars to the right indicate a longer stance time on this side. Note the improvement of symmetry as the subject uses the realtime feedback to modulate her gait.

## Timeline and Cost

Activities	CY	13	14	15	16
Aim 1					
Aim 2					
Aim 3					
<b>Estimated Budget (\$K)</b>		\$382K	\$326 K		

## Goals/Milestones

### CY13 Goals- Preparation

IRB approved

Marker Alignment Device developed and tested

Realtime Software Developed and tested

### CY14 Goals – Data Collection

Retraining Started

Insole Application Developed

### CY15 Goals – Study Completion

Complete Retraining

Complete Analysis

Complete Validation of instrumented insole

### Budget Expenditure to Date

Actual Expenditure: \$666,342

Remaining Budget: \$0

Updated: July 12, 2017

## APPENDIX E



## BADER Toolbox Focus Group Methods and Results

**Purpose:** To learn what are the physical, emotional, and social changes that affect one's life after major extremity trauma, with or without amputation; to obtain this information directly from individuals who have sustained these injuries, as well as from clinicians who treat them, without assumptions or biases.

**Focus Groups:** Using the same methodology as other modern measurement initiatives (e.g., PROMIS and Neuro-QOL), we conducted focus groups at 3 Military Treatment Facilities and 1 VA Medical Center. Groups were conducted with individuals with (1) upper extremity amputation; (2) lower extremity amputation; (3) limb preservation, as well as with (4) expert clinicians. There were typically two moderators, and the groups lasted between 60-90 minutes. The moderator began the session with an open-ended question such as, "How has your life been affected by your injury and rehabilitation?" The moderator then helped guide the discussion to include all participants and multiple areas of health and wellness. During the groups, participants referred to one another by randomly assigned colors (e.g., "Mr. Blue") to maximize confidentiality.

Table 1. Patient Groups, by Injury Category

Injury Category	n	% of total
Upper Extremity (UE) Amputation	12	21.4
Lower Extremity (LE) Amputation	16	28.6
Limb Preservation (UE and/or LE)	21	37.5
Multiple (combination of above diagnoses)	7	12.5
Total Patients	56	

Table 2. Provider Groups, by Discipline

Provider Discipline	n	% of total
Physical Therapist	8	23.5
Prosthetist and/or Orthotist	8	23.5
Physiatrist	6	17.6
Occupational Therapist	5	14.7
Psychologist	2	5.8
Nurse	2	5.8
Recreational Therapist	2	5.8
Kinesiotherapist	1	2.9
Total Providers	34	

**Qualitative Analyses:** The focus groups were audio-recorded, transcribed verbatim, and then parsed into segments of text that communicated a single idea ("chunks"). Concepts ("codes," like *depression*) were identified by two independent raters, and compiled into a "codebook." Codes were organized hierarchically such that *depression* was nested under *emotions*. Two independent raters then applied a code to each chunk of text, one code per chunk, and coding differences were reconciled by a third rater.

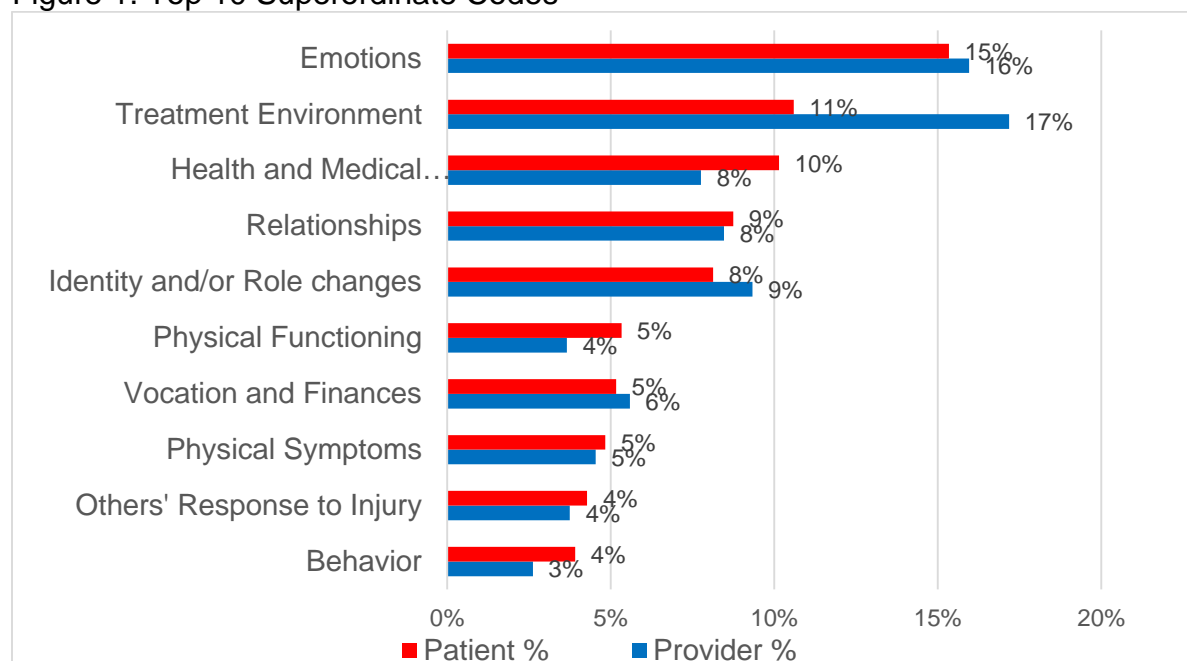
Frequencies of codes were then tallied, and reported by group and by hierarchy within the codebook.

**Results:** In total, 106 codes were applied to 7,850 chunks. Figure 1 shows the 10 superordinate categories with the most chunks. Within the superordinate category, *Emotions*, the ordinate code with the most chunks was *Resilience* (28% of patient comments about emotions). A good example of a comment about resilience came from a participant with upper extremity amputation. He said: “You see everybody else doing all this stuff you used to do, and you can’t do it! But you have to find a new normal. Keep pushing.” Participants also commonly discussed feelings of *Anger* (11% of patient comments about emotions), *Motivation/Perseverance* (10%), *Anxiety* (8%), *Depression* (6%), and *Body Image* (4%).

Ordinate codes under *Treatment Environment* captured statements about the *Quality of Healthcare and the Healthcare Facility* (34% of patient comments about Treatment Environment), as well as the social environment of treatment. Specifically, 28% of patient comments under *Treatment Environment* were about *Social Comparison* – that is, comparing one’s own situation that of another (e.g., “Well at least I don’t have it that bad!”).

Ordinate codes under *Identity and/or Role Change* captured statements about changing identity/role as a *Service Member* (28% of comments about Identity/Role Change), about *One who is Injured or Disabled* (12%), and about changing *Role within the Family* (10%).

Figure 1. Top 10 Superordinate Codes



Note: Percentages reflect the number of chunks within each superordinate code, divided by the total number of chunks for each group.



Table 3 shows 10 codes with the most chunks, regardless of their position within the conceptual hierarchy, separated by category of participant. Cells highlighted in blue indicate codes that are unique to that group's "top 10." This may indicate experiences that are relatively salient for that group.

Table 3. Top 10 Codes by Group

Upper Limb Amputation	Lower Limb Amputation	Limb Preservation	Providers
Orthosis or prosthesis	(Role change) service member	Pain	Quality of healthcare and facility
Resilience	Military employment	Resilience	Social comparison
Quality of healthcare and facility	Social comparison	Medication	Romantic relationships
Romantic relationships	Romantic relationships	Quality of healthcare and facility	Pre-existing conditions
Injured person's response to others	Quality of healthcare and facility	Orthosis or prosthesis	Resilience
Family relationships	Resilience	Military employment	Orthosis or prosthesis
Social comparison	Injured person's response to others	Type of physical activity	Other emotions - negative
Type of physical activity	Military relationships	Family relationships	(Physical recovery) progress
Self care and general tasks	Social environment of treatment	Injured person's response to others	(Role change) service member
Social environment of treatment	Family relationships	Other emotions - negative	Motivation/perseverance

**Summary and Implications:** Discussion of psychosocial issues was much more prominent than discussion of physical limitations. When physical issues were discussed, it was in the context of barriers to participation and employment. In particular, patients and providers discussed:

- Resilience and emotions
- Changing identities, life roles, and family relationships
- Understanding their condition in relation to others
- The quality of their healthcare and resources
- The orthosis/prosthesis itself
- Self-esteem/body image
- Grief and loss

These results suggest that comprehensive assessment should include evaluation of psychosocial issues in addition to global quality of life and performance-based measures. Assessment of these additional issues is beyond the scope of the current project, but should be included in future follow up work.

## APPENDIX F



# BADER CONSORTIUM

REHABILITATION OUTCOMES

MEASUREMENT CORE

Patient Reported Outcomes Assessment

## Training Manual

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# 1.0 BENEFITS OF USING ASSESSMENT CENTER

- ▶ Assessment Center is a free to use online platform for assessment creation, development, and administration.
- ▶ Assessment Center is HIPAA compliant and utilizes high security standards to ensure the study data remains secure. The study administrator controls permissions for users – users will only have access to what they are allowed to access.
- ▶ The ability to add any assessment instrument to the study allows you to use similar measures side-by-side. This would allow for the comparison of the results from a measure that you have used in the past with a new measure, as well as comparing results from short forms versus CATs.

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## ABOUT THIS TRAINING MANUAL

This guide is intended as a supplement to the Assessment Center manual.

- ▶ The manual can be found on <https://www.assessmentcenter.net>
  - On the left side of the page is a list of helpful resources that includes user manuals.
- ▶ Notice the 3 different ways to contact Assessment Center for help.
  - When contacting Assessment Center about a problem with your study, please be as specific as you can with details such as study name, instrument name and item ID.

### Resources

[Instrument Library](#)

[Scoring Manuals](#)

[Workshops](#)

[Publications](#)

[Presentations](#)

[User Manuals](#)

[Glossary](#)

[Terms and Conditions](#)

[FAQ](#)

[Release History](#)

[Usage Statistics](#)

[About Us](#)

[Video Tutorials](#)

### Contact Us

[help@assessmentcenter.net](mailto:help@assessmentcenter.net)  
Help Line: 877-283-0596

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## 3.0 USER REGISTRATION

Before you begin working with Assessment Center, you will need to register.

- Go to <https://www.assessmentcenter.net>
- Click on “Register New User” in the top right of the screen



The screenshot shows the top navigation bar of the Assessment Center website. It includes a 'Login' text input field, a 'Password' text input field, a 'Continue' button, and a 'Register New User' link circled in red. There is also a 'Forgot Password' link.

*\*If you have already registered, but forgotten your password, click on “Forgot Password”.*

### 3.1 USER REGISTRATION – STEP 1

Step 1 of the registration process includes creating a login and password

- ▶ Choosing a strong password at this point is a critical step in keeping your study secure.
- ▶ It is required to be at least 6 characters.
- ▶ A strong password would be 8 or more characters and include upper & lowercase, numbers, and special characters (e.g., # \$ @)

**Registration step 1: Please complete fields below.**



The screenshot shows the 'Registration step 1' form. It includes fields for Login\*, Password\*, Re-enter Password\*, Title, First Name\*, Last Name\*, Institution\*, Email\*, Re-enter Email\*, Phone, Mailing Address, City, State/Province (a dropdown menu with 'Please Select' and a downward arrow), Country, and Postal Code. There are 'Save' and 'Cancel' buttons at the top right. A red circle highlights the text '(\*) fields are required.' at the bottom.

### 3.2 USER REGISTRATION – TERMS & CONDITIONS

You will be required to read and accept the Assessment Center terms & conditions.

**Assessment Center**

**ASSESSMENT CENTER TERMS AND CONDITIONS**

Last Updated 1/21/2011

You understand and agree that the services that Northwestern University - Department of Medical Social Sciences (NU-MSS) provides to you through the Assessment Center websites are subject to the following Terms and Conditions (TAC). NU-MSS reserves the right to update the TAC at any time. Changes in the TAC will apply to new users and to new projects created by existing users after these changes are posted. The most current version of the TAC can be reviewed by clicking on the "Terms and Conditions" hypertext link located on the Assessment Center Home page.

**DESCRIPTION OF SERVICES.**

Assessment Center provides you with access to a variety of resources, including survey measures, study administration, data management, and storage of statistical analysis results (collectively, the "Services"). The Services, including any updates, enhancements, and/or new features are subject to the TAC, and your use of the Services constitutes acceptance of all terms and conditions set forth in the TAC.

**PRIVACY AND PROTECTION OF PERSONAL INFORMATION.**

Accept Cancel

Mailing Address

### 3.3 USER REGISTRATION – STEP 2

- After accepting the terms & conditions, an email will be sent to the email address you registered with. Follow those instructions to activate your account.

Subject: Assessment Center Registration: Validation Required

Thank you for your interest in Assessment Center.

To use the Assessment Center application, you must verify your email address by clicking on the hyperlink below and entering the login and password you created during step one of registration.

<https://www.assessmentcenter.net/ac1/Default.aspx?Login=pktest>

You are responsible for maintaining the confidentiality of your password and account and for any and all activities that occur under your account. Please notify us immediately of any unauthorized use.

As a registered user, you agreed and are responsible for adhering to all the Assessment Center Terms and Conditions of use which can be accessed at <https://www.assessmentcenter.net/TandC.aspx>. Instruments within Assessment Center may have instrument Terms and Conditions which you will be required to endorse prior to use.

The information and materials available in Assessment Center are subject to protection under the copyright laws of the United States and other countries. All rights reserved.

Should you have any questions, please contact the Assessment Center team via email at [help@assessmentcenter.net](mailto:help@assessmentcenter.net).

Thanks again for your interest in Assessment Center.

- The link in the email will take you to a special login screen. Here is where you will enter the login and password you used to register.

## Welcome to Assessment Center<sup>SM</sup>

Please enter your User ID and Password below to access the center.

When you enter the site, the study information you provided at registration will automatically be included in your studies list.

You may begin work on this study immediately or create an additional study.

- Registration Step 3: Your registration is almost complete. To complete your registration, please enter the login and password you created during registration step 1 in the fields below and click Continue.

User ID:

Password:

[Forgot Password](#)

If at any time you have any questions or difficulties, please contact the Center Administrators by email to [help@assessmentcenter.net](mailto:help@assessmentcenter.net)

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## 4.0 NAVIGATING ASSESSMENT CENTER

Assessment Center's functions are split up into 5 tabs.

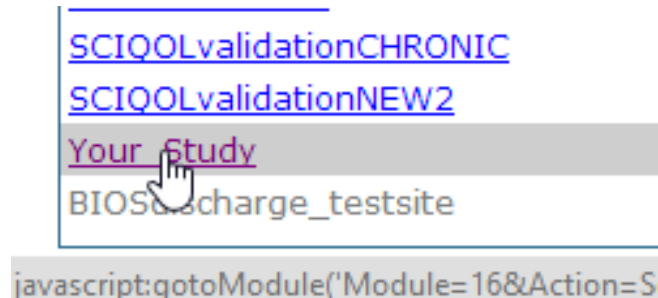
- The next set of slides will give a brief overview of each tab
- Step-by-step instructions will follow the overview

### 4.1 STUDIES TAB



The Studies tab contains a list of all the studies you are a part of.

- The study that is currently selected will be at the top of the list. To select a



study, click on the title of the study.

- The currently selected study will also be displayed at the top right of the



screen

## 4.2 INSTRUMENTS TAB

The Instruments tab shows the list of instruments in your study.



Studies Instruments Set-up Preview Administration PDFs My Account Help Logout

Current Study: Your\_Study

Study Content (Your\_Study)

### Study Content

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Order	Name	Administration Study	Include	Terms of Use
1	PROMIS Bank v1.0 - Anger	PROMIS	<input checked="" type="checkbox"/>	Notes
3	Happiness Rating Scale	Your_Study	<input checked="" type="checkbox"/>	Notes
3	PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS	<input checked="" type="checkbox"/>	Notes

- From this page you can also add, create, and edit instruments.

#### 4.2.1 BREADCRUMB TRAIL

The Instruments tab also has a “breadcrumb trail” that makes finding your location easy.

- The breadcrumb trail is found at the top of the page. It shows your current location and allows you to quickly move up levels (e.g., from Item Details to Instrument Detail) by clicking where you would like to navigate.

Studies Instruments Set-up Preview Administration

[Study Content \(Your Study\)](#) >> [Instrument Detail \(Happiness Rating Scale\)](#) >> Item Details (happiness\_2)

### Item Detail

#### 4.3 SET-UP TAB

Studies Instruments Set-up Preview Administration

[Language](#) | [Basic](#) | [Advanced](#) | [Consent](#) | [Registration](#) |

The Set-up tab has five subsections that allow you to customize the way the study functions as well as the consent and registration process

#### 4.4 PREVIEW TAB

The Preview tab is the tab that allows you to review the study to ensure it has all of the content and functions properly

- ▶ When the study is ready, you will move on to the “Launch Study” section
- ▶ Once a study is launched, it cannot be edited

#### 4.5 ADMINISTRATION TAB

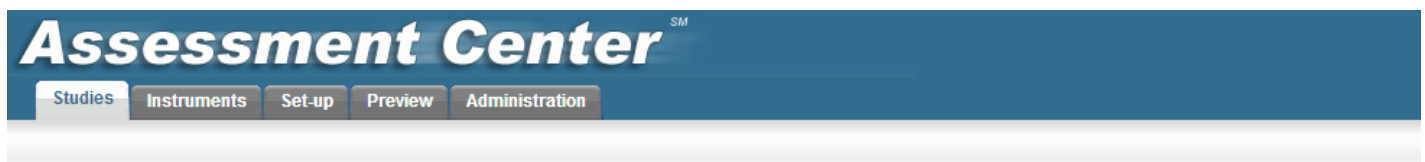
This tab has functions for before and after launch of the study.

<i>Before Launch</i>	<i>After Launch</i>
<ul style="list-style-type: none"><li>▪ Create “test” participants</li><li>▪ View and alter “test” participants’ schedule Of assessments</li></ul>	<ul style="list-style-type: none"><li>▪ Register participants</li><li>▪ Download data</li><li>▪ Download reports such as data dictionary</li><li>▪ Review progress and other statistics about the study</li><li>▪ Modify participants’ assessment schedules</li></ul>

---

## 5.0 CREATING A STUDY ON ASSESSMENT CENTER

A study can be created in two steps:



Study List (Your\_Study)

## Study List

To get started, please select an existing study or create a new one. Then continue work in the system by selecting from the tabs above.

Create New Study

To select, click on study name:

Step 1: on the “Studies” tab click on “Create New Study.”

The image shows a web form titled "Study Properties". At the top, there is a breadcrumb link: "Study List (Your Study) >> Study Properties". The form contains three main input fields: "Name of Study\*" with a text box, "Description\*" with a larger text area, and "Study Status\*" with two radio button options: "Active" (which is selected) and "Archived". To the right of the "Name of Study" field are two buttons: "Save" and "Back". At the bottom of the form, there is a note: "(\*) fields are required."

Step 2: fill in the name of the study, and a brief description. Then click “Save”.

## 5.1 ADDING INSTRUMENTS TO YOUR STUDY

Now that your study is created, the next step is to add instruments.

- ▶ There are a number of publicly available studies / instruments that can be added to your study.
- ▶ You can also create your own instruments or add instruments that are not publicly available on Assessment Center.

### 5.1.1 INSTRUMENTS AVAILABLE ON ASSESSMENT CENTER

Publicly Available	By Request
PROMIS	SCI-QOL
NeuroQOL	TBI-QOL

## 5.2 ADDING INSTRUMENTS TO YOUR STUDY

The first step in creating or adding an instrument is found in the “Instruments” tab. Here you see options for adding and creating instruments.

Study Content (Your\_Study)

### Study Content

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Study Content				
Order	Name	Administration Study	Include	Terms of Use



- ▶ To add an instrument, click “Add”.
- ▶ To add a PROMIS instrument to your study follow these steps:
  - In the “Study:” box, select “PROMIS”

[Study Content \(Your\\_Study\)](#) >> Add an Instrument

### Add an Instrument

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

- ☒ Instrument  
☐ Battery

Study:

PROMIS

Type:

All

Domain:

All

Show Results

### Search Results

- Click on “Show Results”

### Search Results

Add to Study					
Select	Name	Administration Study	Type	Domain	Terms of Use
<input checked="" type="checkbox"/>	PROMIS Bank v1.0 - Anger	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Emotional Distress/Negative Affect, Anger	<a href="#">Statistics</a> ©
<input type="checkbox"/>	PROMIS Bank v1.0 - Anxiety	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Emotional Distress/Negative Affect, Anxiety/Fear	<a href="#">Statistics</a> ©
<input type="checkbox"/>	PROMIS Bank v1.0 - Applied Cog Abilities	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Abilities	<a href="#">Statistics</a> ©

- Now, you will be presented with a list of available PROMIS instruments.

- ▶ To explore the individual items of the instruments, click on the + symbol next to the instrument's name. This will expand the instrument so you can view the text of each item and the response choices.
- ▶ To select an instrument for your study, put a checkmark into the box for that instrument.
- ▶ You can review and accept the terms of use by clicking on the © symbol
- ▶ To add the instrument, click “Add to Study”

Click on the Instruments tab to see the instrument(s) that were added to your study.

[Study Content \(Your\\_Study\)](#)

### Study Content

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

Add Save Create

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Study Content									
Order	Name	Administration Study					Include	Terms of Use	
1	PROMIS Bank v1.0 - Anger	PROMIS	<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>	<input checked="" type="checkbox"/>	Notes	©

## 5.3 PROMIS INSTRUMENTS AVAILABLE ON ASSESSMENT CENTER

### **Pediatric / Parent Proxy PROMIS Instruments**

Domain	Instrument Name	Item Bank / CAT	Short Form	Short Forms Available
Emotional	Parent Proxy Anxiety	✓	✓	6a
	Parent Proxy Depressive Symptoms	✓	✓	8a
	Pediatric Anger		✓	8a
	Pediatric Anxiety	✓	✓	8a
	Pediatric Depressive Symptoms	✓	✓	8b
Fatigue	Parent Proxy Fatigue	✓	✓	10a
	Pediatric Fatigue	✓	✓	10a
Other	Parent Proxy Asthma	✓	✓	8a
	Pediatric Asthma	✓	✓	8a
Pain	Parent Proxy Pain Interference	✓	✓	8a
	Pediatric Pain Interference	✓	✓	8a
Physical Function	Parent Proxy Mobility	✓	✓	8a
	Parent Proxy Upper Extremity	✓	✓	8a
	Pediatric Mobility	✓	✓	8a
	Pediatric Upper Extremity	✓	✓	8a
Social	Parent Proxy Peer Relations	✓	✓	7a
	Pediatric Peer Relations	✓	✓	7a

### **Adult PROMIS Instruments**

Domain	Instrument Name	Item Bank / CAT	Short Form	Short Forms Available
--------	-----------------	-----------------	------------	-----------------------

Alcohol	Alcohol: Alcohol Use	✓	✓	7a
	Alcohol: Negative Consequences	✓	✓	7a
	Alcohol: Negative Expectancies	✓	✓	7a
	Alcohol: Positive Consequences	✓	✓	7a
	Alcohol: Positive Expectancies	✓	✓	7a
Applied Cognition	Applied Cog Abilities	✓	✓	4a, 6a, 8a
	Applied Cog General Concerns	✓	✓	4a, 6a, 8a
Emotional	Anger	✓	✓	4a
	Anxiety	✓	✓	4a, 6a, 7a, 8a
	Depression	✓	✓	4a, 6a, 8a, 8b
Fatigue	Fatigue	✓	✓	4a, 6a, 7a, 8a
Pain	Pain Behavior	✓	✓	6b
	Pain Intensity		✓	7a
	Pain Interference	✓	✓	4a, 6a, 6b, 8a
Physical Function	Physical Function	✓	✓	4a, 6a, 8a, 10a, 20a
	Physical Function Samples w Mobility Aid	✓	✓	10a
Psychosocial Illness Impact	Psychosocial Illness Impact-Neg	✓	✓	4a ,8a
	Psychosocial Illness Impact-Pos	✓	✓	4a ,8a
Quality of Social Support	Companionship		✓	4a, 6a
	Emotional Support	✓	✓	4a, 6a, 8a
	Informational Support	✓	✓	4a, 6a, 8a
	Instrumental Support	✓	✓	4a, 6a, 8a
Sexual Function	Anal Discomfort		✓	
	Erectile Function		✓	
	Global Satisfaction w Sex		✓	

	Life			
	Interest in Sexual Activity		✓	
	Interfering Factors		✓	
	Lubrication		✓	
	Orgasm		✓	
	Sexual Activities		✓	
	Sexual Function Profile- Female		✓	
	Sexual Function Profile- Male		✓	
	Sexual Function Profile - Male&Female		✓	
	Sexual Function Screener Questions		✓	
	Therapeutic Aids		✓	
	Vaginal Discomfort		✓	
Sleep	Sleep Disturbance	✓	✓	4a, 6a, 8a
	Sleep-Related Impairment	✓	✓	8a
Social	Ability to Participate in Social Roles and Activities	✓	✓	4a, 6a, 8a
	Satisfaction with Participation in Discretionary Social Activities	✓	✓	7a
	Satisfaction with Participation in Social Roles	✓	✓	4a, 6a, 8a
	Satisfaction with Social Roles and Activities	✓	✓	4a, 6a, 8a
	Social Isolation	✓	✓	4a, 6a, 8a

### Profile PROMIS Instruments

Domain	Instrument Name	Short Forms Available
--------	-----------------	-----------------------------



Multiple (Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Satisfaction with Social Roles, Anxiety/Fear, Depression/Sadness)	Profile	29, 43, 57
Multiple (Pain, Fatigue, Physical Function, Emotional Distress/Negative Affect, Other, Pain Intensity, Pain Interference, Mobility, Anxiety/Fear, Depression/Sadness)	Pediatric Profile	25, 37, 49
Multiple (Pain, Fatigue, Physical Function, Other, Anxiety/Fear, Depression/Sadness, Satisfaction with Social Roles and Activities)	Global Health	

---

**\*All profile instruments are short forms**

## 6.0 CREATING AN INSTRUMENT

The instruments you want to use for your study may not be available on Assessment Center. You can use the creation tools in Assessment Center to include those instruments into your study.

User-created instruments can be used seamlessly with publicly available instruments.

To begin, go to the “Study Content” page. Here you will click “Create”

**Study Content**

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

Add Save Create

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Study Content				
Order	Name	Administration Study	Include	Terms of Use

**Item Detail**

Save Cancel

ID\*: happiness\_1

Domain\*

- Ability to Participate in Social Roles/Activities
- Satisfaction with Social Roles and Activities
- Satisfaction with Discretionary Social Activities
- Satisfaction with Social Roles
- Social Isolation
- Social Relationships
- Stigma
- Stress
- Urinary/Bladder Function
- Other

Item Contains Protected Health Information (PHI) ☐

Context

When you first woke up...<br><br>

Stem\*

How happy were you this morning?

Responses

Type: Multiple Choice

Add another row

Score	Response Text	Show Response Score
1	Very Unhappy	<input type="checkbox"/> Delete
2	Somewhat Unhappy	<input type="checkbox"/> Delete
3	Somewhat Happy	<input type="checkbox"/> Delete
4	Very Happy	<input type="checkbox"/> Delete

Administration Your\_Study

Original Instrument: Happiness Rating Scale

Creation Date: 6/21/2013

Show Item History

## 6.1 CREATING INDIVIDUAL ITEMS FOR AN INSTRUMENT

Assessment Center allows for 3 types of HTML code to be used when creating individual items.

- ▶ line breaks are created by adding in <br> where you want a line break. A good separation for context and stem is three line breaks (<br><br><br>).
- ▶ Underlining is accomplished by putting <u> & </u> on either side of the text you want underlined (In the last <u>month</u>). The “/” character ends the code.
- ▶ Italics is done similarly to underlining. The code is <i> & </i>.

Context In the last <u>month</u>   
Stem* <i>have you been happy?</i>

In the example, you will see the code and resulting item from the code with and without the line breaks

The screenshot shows the 'Assessment Center' software interface. A 'Save' popup window is open, displaying the following fields:

- Item History Category\***: A dropdown menu with 'New Item' selected.
- Date\***: A text box containing '6/21/2013'.
- Comments/Reasons for Changes\***: A large text area for entering notes.
- Buttons**: 'Save' and 'Cancel' buttons at the bottom of the popup.

In the background, two examples of item stems are visible:

- Left Example**: In the last month  
have you been happy?
- Right Example**: In the last month

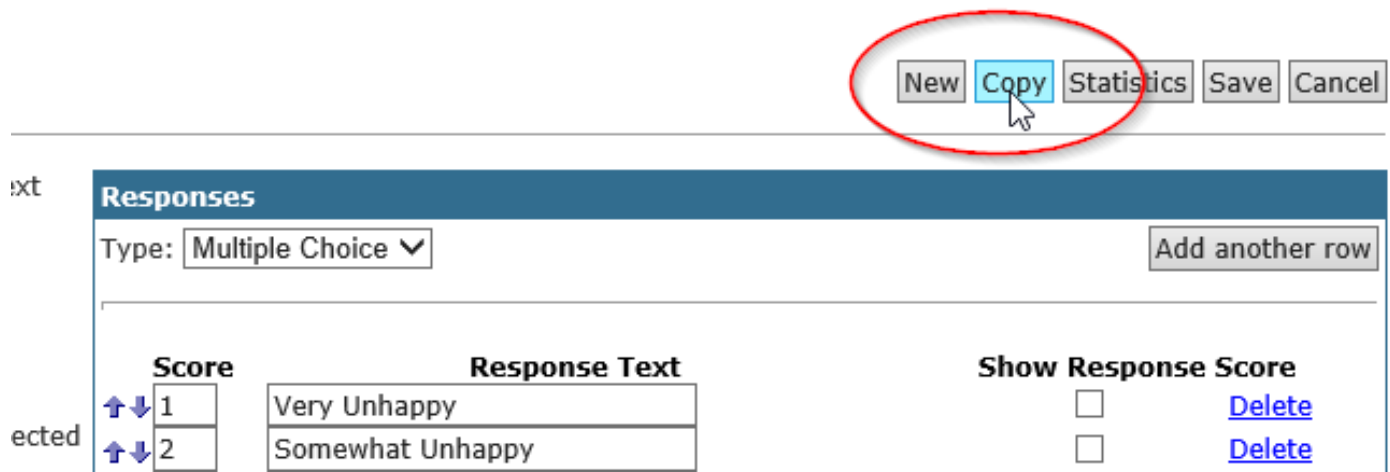
After you have finished creating an item and clicking “Save”, a popup window will appear for you to enter any notes about the item.

- ▶ For new items, comments are not required.
- ▶ For edited items, you must select an Item History Category and enter at least one character into the Comments box.

► Click Save when you are done

## 6.2 COPYING INDIVIDUAL ITEMS FOR AN INSTRUMENT

Many instruments will have items with the same response options or context. Assessment Center allows you to copy an item by clicking on “Copy”



The screenshot shows the 'Responses' section of the Assessment Center interface. At the top, there are buttons for 'New', 'Copy', 'Statistics', 'Save', and 'Cancel'. The 'Copy' button is highlighted with a red circle. Below this, there is a table with two columns: 'Score' and 'Response Text'. The table contains two rows: one with a score of 1 and the text 'Very Unhappy', and another with a score of 2 and the text 'Somewhat Unhappy'. To the right of the table, there are checkboxes for 'Show Response Score' and 'Delete' links for each row.

Score	Response Text	Show Response Score	
1	Very Unhappy	<input type="checkbox"/>	<a href="#">Delete</a>
2	Somewhat Unhappy	<input type="checkbox"/>	<a href="#">Delete</a>

This copied item will be identical to the original item except you must provide a unique item ID

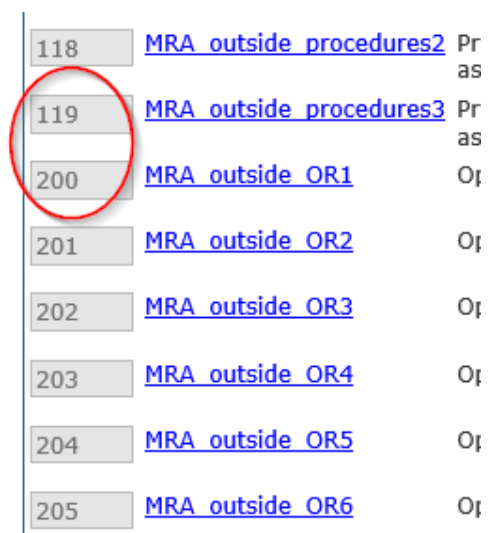
## 7.0 CHANGING THE ORDER OF INDIVIDUAL ITEMS

The Instrument Detail Screen is reached by clicking on the name of an instrument

Here you can edit the order of the items.

When you have finished ordering, click “Save”

*\*Assessment Center will timeout after 5 minutes of inactivity. Keep this in mind when re-ordering items. If you timeout, your progress will not be saved.*



The screenshot shows a list of items in the Instrument Detail Screen. The items are listed in a table with columns for item ID, item name, and a status or type. Item 119, 'MRA outside procedures3', is highlighted with a red circle.

Item ID	Item Name	Status/Type
118	MRA outside procedures2	Pr as
119	MRA outside procedures3	Pr as
200	MRA outside OR1	Oi
201	MRA outside OR2	Oi
202	MRA outside OR3	Oi
203	MRA outside OR4	Oi
204	MRA outside OR5	Oi
205	MRA outside OR6	Oi

*\*it can be helpful for instruments that are a “work in progress” to group the items as shown in the example. This makes it easier to add an item to a section without having to renumber all of the items (e.g., adding in an item at #2 and having to renumber items 2-200)*

## 8.0 CUSTOMIZING INSTRUMENTS

On the study content page, there are options for customizing, previewing, and editing the properties of instruments.

Study Content									
Order	Name	Administration	Study					Include	Terms of Use
1	PROMIS Bank v1.0 - Anger	PROMIS		<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>	<input checked="" type="checkbox"/>	Notes
2	PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS		<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>	<input checked="" type="checkbox"/>	Notes
3	<u>Happiness Rating Scale</u>	Your_Study		<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>	<input checked="" type="checkbox"/>	Notes

- The next step is setting up the instrument so it functions properly
- Click on “Customize”

## 9.0 CREATING AN INSTRUMENT

[Study Content \(Your Study\)](#) >> Instrument Properties

### Instrument Properties

Name\* 
Save Back

Select the domain or domains for this instrument\*

- Ability to Participate in Social Roles/Activities  
- Satisfaction with Social Roles and Activities  
- - Satisfaction with Discretionary Social Activities  
- - Satisfaction with Social Roles  
Social Isolation  
Social Relationships  
Stigma  
Stress  
Urinary/Bladder Function  
Other

Language: 
Status: 
Type\*: 
IRT Model:

Description\*

Comments

1. The name must be unique in Assessment Center
2. Select the appropriate domain that describes the instrument
3. Enter a brief description
4. Choose “under development”
5. Choose the type of instrument [For nearly all purposes this will be “Short Form”]
6. Click “Save”

---

## 10.0 CUSTOMIZING INSTRUMENTS

In the top left of the screen are the “Administration Method” options.

- The options are Sequential [in order], Random, and Branch.

Templates determine how an item will appear to study respondents on the data collection screens.

The screenshot shows a web interface for customizing IRT parameters. At the top, a text label states: "Templates determine how an item will appear to study respondents on the data collection screens." Below this, there are three rows of dropdown menus. The first row is labeled "Change all item templates to:" and has a dropdown menu with "Please select" and a downward arrow, which is circled in red. The second row is labeled "Then Go To" and "Template". The "Then Go To" dropdown has "Please Select" and a downward arrow. The "Template" dropdown has "Vertical 01" and a downward arrow, which is also circled in red. The third row has two dropdown menus, both with "Please Select" and a downward arrow, and "Vertical 01" and a downward arrow.

*\*If your instrument has specific IRT Parameters, or if you'd like to modify the IRT parameters [e.g., min/max # of items, max standard error] for an existing item*

[Study Content \(Your Study\)](#) >> Instrument Customization

## Instrument Customization

Instrument: Happiness Rating Scale

Administration Method: Sequential ▼

Set IRT Parameters

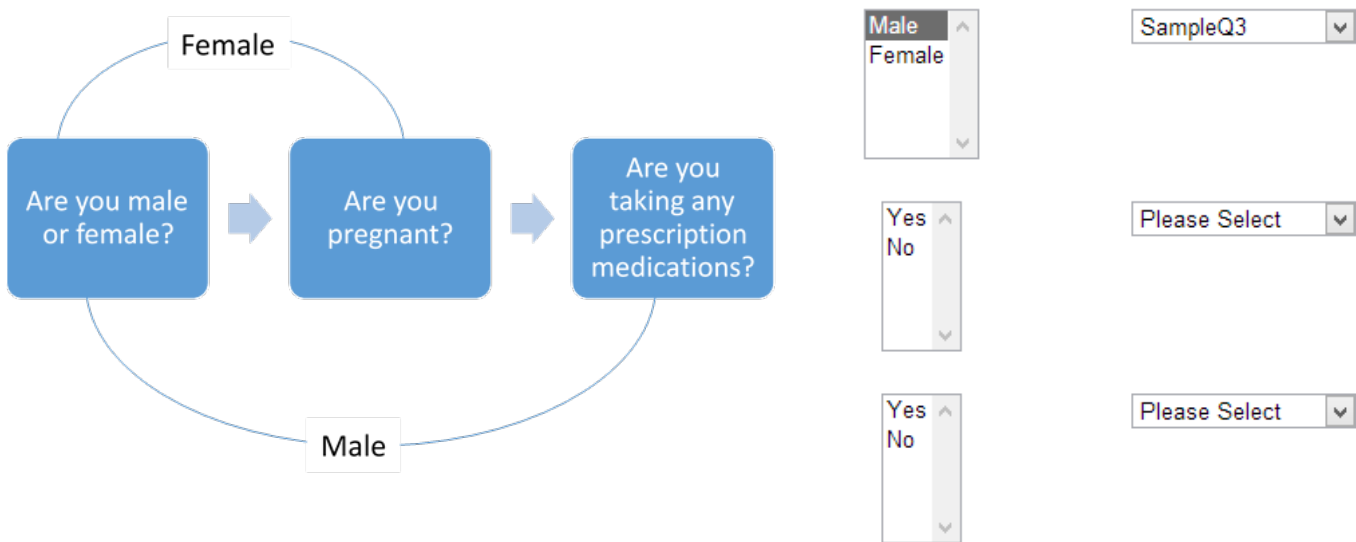
Instrument order is Sequential. Define blocks and template criteria below.

☐ Randomize Item Blocks ☐ Randomize Items within Item Blocks

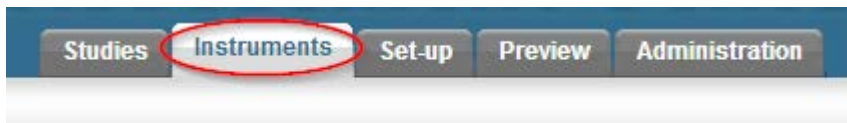
*bank/CAT, those settings are accessed by clicking on “Set IRT Parameters”*

- ▶ The appearance of the items can also be customized.
  - All items can be changed to have one template or the template for each individual item can be set.

- Items can be set to “Auto Advance” – once a response is chosen, that response is saved and the next item is displayed
- ▶ Choosing Branch as the administration method allows you to set skip logic for the instrument.
- ▶ When certain criteria are met, an item or items are skipped. This is helpful in instances where some responses require more information or do not apply to the participant (e.g., female-related items skipped for male participants).
- ▶ The branching function only works by skipping the next item or set of items. For example, A screener question at the beginning cannot be set to skip items at the end of the instrument



## 11.0 ITEM-LEVEL QUALITY ASSURANCE



It is highly recommended that you preview each instrument to ensure that it functions how you want it to function.



*\*Once a study is launched, it is not possible to change the instruments.*

Study Content				
Order	Name	Administration Study		
1	PROMIS Bank v1.0 - Anger	PROMIS	<a href="#">Customize</a>	<a href="#">Preview</a>
2	PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS	<a href="#">Customize</a>	<a href="#">Preview</a>
3	<a href="#">Happiness Rating Scale</a>	Your_Study	<a href="#">Customize</a>	<a href="#">Preview</a>

There are two options for previewing and it is recommended to do both of them.

-----

- ☒ Preview item list
- ☐ Simulate instrument administration with customized settings
- ☐ Show Execution Detail (e.g. Item ID and Ability Estimate)

Language: English

Continue Cancel

- The first option is to preview the item list.
  - Best for checking for typos and other errors when the individual items were entered.
  - This view displays all of the items in one list.

**Assessment Center**

[happiness\_1]

**When you first woke up...**

**How happy were you this morning?**

☐ Very Unhappy  
☐ Somewhat Unhappy  
☐ Somewhat Happy  
☐ Very Happy

---

[happiness\_2]

**When you first woke up...**

**How rested did you feel?**

☐ Very tired  
☐ Somewhat tired  
☐ Somewhat rested  
☐ Well rested

- The second type of preview is a simulation of what the participant would

**When you first woke up...**

**How happy were you this morning?**

☐ Very Unhappy

☐ Somewhat Unhappy

☐ Somewhat Happy

☐ Very Happy

Previous      Next      Exit

The area inside the box is what is displayed during full previews and live studies

see.

---

## 12.0 QUALITY ASSURANCE

The simulation option also allows you to:

- Test-drive instrument customization settings such as IRT, branching, and

<https://www.assessmentcenter.net/ac1/Modules/PreviewInstrumentOptions.aspx?InstrumentID=2e16caae0e0c4749b4d21578ef2fafc5&Type=ShortForm>

**View Options**

☐ Preview item list

☒ Simulate instrument administration with customized settings

☐ Show Execution Detail (e.g. Item ID and Ability Estimate)

Language: English ▼

Continue      Cancel

randomization.

- Only the area inside the box is displayed in live studies.

---

## 13.0 SETTING UP YOUR STUDY



- The first step is to select the language. Currently only English and Spanish are available.
  - This choice affects the language of the buttons on each page as well as screens set by Assessment Center.
  - PROMIS measures that are available in Spanish will change to Spanish if you choose that as your language.
  - User-created instruments and welcome screens are not affected.



Language (Your\_Study)

## Language

In what language(s) would you like to administer your study?

☐ English

☐ Spanish

### ► Step 2 is Basic settings

Basic Study Setup (Your\_Study)

#### Basic Study Setup

You may define participant registration forms below.

Start Date\*:

Accrual End Date\*:

Close data collection when sample size equals\*:

Contact information for participant questions\*:

URL Extension\*:

\*All boxes are required

Save Cancel

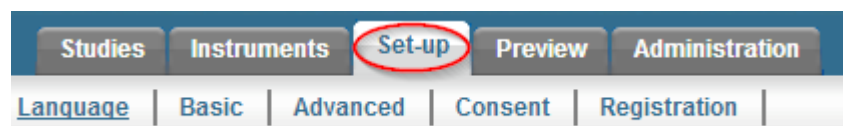
Login screen welcome message (maximum 10,000 characters)

English

**Welcome to Your\_Study**

body p span span span

## 13.1 SETTING UP YOUR STUDY



### ► Step 3 is Advanced Study Setup

## Advanced Study Setup

Create at least one arm/assessment instance and click Save. You will then be able to click on the Specify Instruments link.

<input type="button" value="New Row"/>				
Arm	Assessment	Day Assessment Opens	Window	
<input type="text" value="Type arm name here"/>	<input type="text"/>	Day <input type="text"/>	<input type="text"/> Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>

- This is where the arms of the study, longitudinal intervals, and instruments for each arm/interval are set.

## 13.2 SETTING UP YOUR STUDY

- Creating the Arms of your study
  - Each arm **MUST** have a baseline
  - The spelling of each set of Arms must be identical or Assessment Center will assume it is a new Arm
  - Choose when the assessment windows opens and for how many days it will be open.

<a href="#">New Row</a>					
Arm	Assessment	Day Assessment Opens	Window		
Adult	1	Day 0	5 Days	<a href="#">Specify Instruments</a>	<a href="#">Delete</a>
Adult	2	Day 170	40 Days	<a href="#">Specify Instruments</a>	<a href="#">Delete</a>
Child	1	Day 0	5 Days	<a href="#">Specify Instruments</a>	<a href="#">Delete</a>
Child	2	Day 170	40 Days	<a href="#">Specify Instruments</a>	<a href="#">Delete</a>

### 13.3 SETTING UP YOUR STUDY

Specify instruments by clicking on “Specify Instruments” on the Advanced Study

[Advanced Study Setup \(Your Study\) >> Specify Instruments](#)

#### Arm / Assessment Details

Arm: Adult

Assessment: 1

[Save](#) [Back](#)

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Bank v1.0 - Anger	1	<input checked="" type="checkbox"/>	CAT
1	Fixed	PROMIS Bank v1.0 - Applied Cog General Concerns	2	<input checked="" type="checkbox"/>	CAT

#### Setup Screen

The options available are:

- ▶ Instrument Block and the order within the block
- ▶ If the instrument is completed by the participant
- ▶ Block Administration – the random option randomizes the order of the instruments, not the individual items of each instrument.
- ▶ Any instruments added after you complete this will be a part of all arms and intervals. Simply navigate back to this page to reorder measures or exclude new measures from specific arms/intervals

## 13.4 SETTING UP YOUR STUDY

In the “Consent” page of the setup, you can copy and paste your informed consent documents.

Consent (Your\_Study)

### Consent Forms

To add up to three consents forms to your study, expand applicable consent boxes and enter information.

**- Consent 1** Include ☐

☐ Consent contains Protected Health Information (PHI)  
☐ Include an endorsement checkbox  
☐ Include an endorsement text entry

**- English**

Endorsement checkbox text

Endorsement text entry text

Please copy and paste your consent form content into the box below.

1

2

3

B

I

U

Font

Size

A

A

## 13.5 SETTING UP YOUR STUDY

The registration section of setup is used to select which items you want to collect for your study.

You can also create custom fields by using the choices on the right.

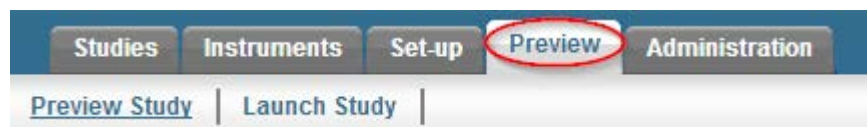
Registration (Your\_Study)

## Registration

You may define participant registration forms below.

Custom Demographic Fields					Additional Custom Fields	
Include	Field Label	Required	Validation			
			Min Value	Max Value		
<input checked="" type="checkbox"/>	Age	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	+ Date Field
<input type="checkbox"/>	Date of Birth	<input type="checkbox"/>			<input type="text"/>	+ Number Field
<input checked="" type="checkbox"/>	Gender	<input type="checkbox"/>			<input type="text"/>	+ Number2 Field
<input checked="" type="checkbox"/>	Ethnicity	<input type="checkbox"/>			<input type="text"/>	+ Text Field
<input checked="" type="checkbox"/>	Race	<input type="checkbox"/>			<input type="text"/>	+ List Field
<input type="checkbox"/>	Doctor	<input type="checkbox"/>			<input type="text"/>	
<input type="checkbox"/>	First Name	<input type="checkbox"/>			<input type="text"/>	
<input type="checkbox"/>	Last Name	<input type="checkbox"/>			<input type="text"/>	
<input type="checkbox"/>	Street	<input type="checkbox"/>			<input type="text"/>	
<input type="checkbox"/>	...	<input type="checkbox"/>			<input type="text"/>	

## 14.0 PREVIEWING THE STUDY



The final step before launching the study is to do a full preview. This allows you to go through the registration, consent, and all instruments in the same way a live participant would.

Logins and passwords can be created for those outside of the team developing the study to preview the “live” version of the study for feedback and quality assurance.

There are 2 steps in the full preview of a study.



Approve

#### REVIEW AND APPROVE YOUR STUDY CONFIGURATION\*

Assessment Center is currently in Beta testing. Please review your Study Setup Summary (below) and click the Export button for your Study Configuration Report. To apply changes to your study, navigate back to your study by using the tab above. If you need assistance in reviewing your study parameters, please contact [help@assessmentcenter.net](mailto:help@assessmentcenter.net)

Export

☐

#### PREVIEW AND APPROVE YOUR STUDY\*

To preview your study, click on the Preview Study button. To apply changes to your study, navigate back to your study by using the links above. It is highly recommended that you preview your study in its entirety prior to launching for data collection.

Preview Study

☐

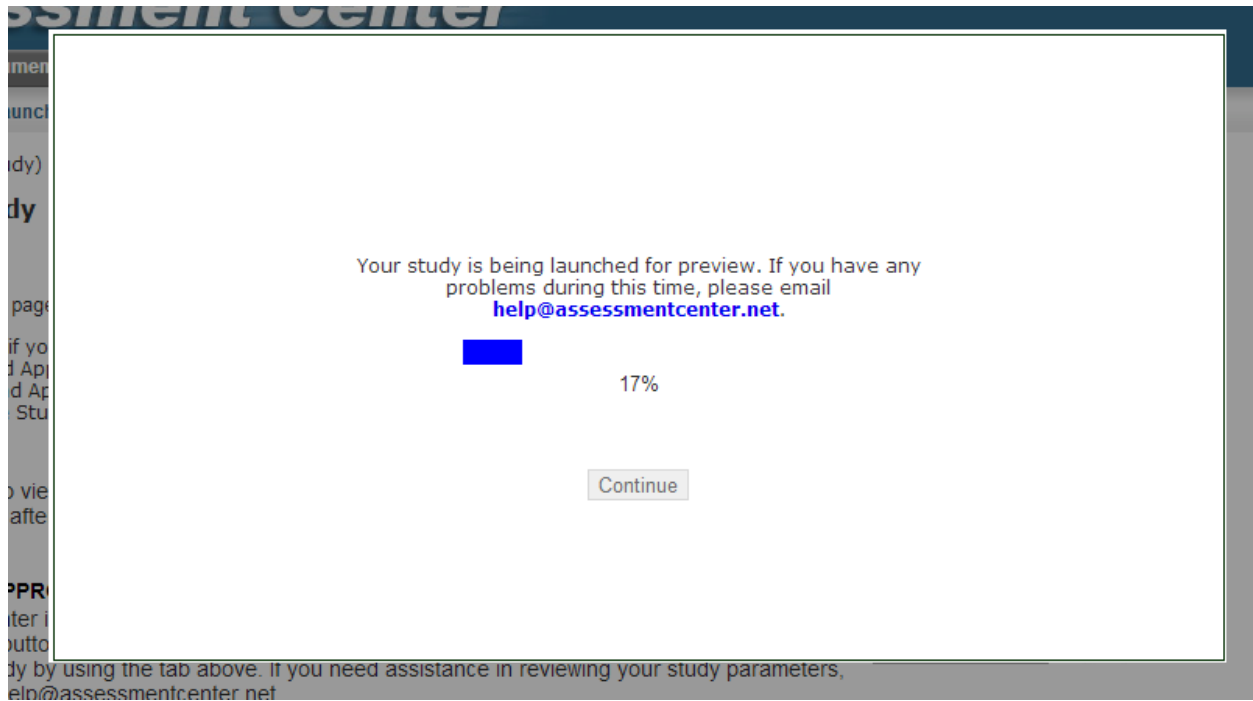
Be sure to review your data exports on the Administration tab prior to launching your study.

- The 1st step is to review the Excel preview of the study
  - The Excel preview contains the information that was set in the “Advanced Study Setup” and instrument customization menus.

2	Study Name: Your_Study								
3	Report Generated: 6/26/2013 12:58:44 PM								
4									
5	Study Arm	Assessme	Schedule	Instrumer	Block Adm	Instrumer	Order wit	Administr	Completed By
6	Child	1	One time	1	Fixed	PROMIS B	1	CAT	Participant
7	Child	1	One time	1	Fixed	PROMIS B	3	CAT	Participant
8	Child	1	One time	1	Fixed	Happiness	3	Branch	Participant
9	Child	1	One time	Not Included		Neuro-QOL Bank v1.0 - Anxiety			
10	Child	2	One time	1	Fixed	PROMIS B	1	CAT	Participant
11	Child	2	One time	1	Fixed	PROMIS B	3	CAT	Participant
12	Child	2	One time	1	Fixed	Happiness	3	Branch	Participant
13	Child	2	One time	Not Included		Neuro-QOL Bank v1.0 - Anxiety			
14	Adult	1	One time	1	Fixed	PROMIS B	1	CAT	Participant
15	Adult	1	One time	1	Fixed	PROMIS B	2	CAT	Participant
16	Adult	1	One time	2	Fixed	Happiness	3	Branch	Participant
17	Adult	1	One time	Not Included		Neuro-QOL Bank v1.0 - Anxiety			
18	Adult	2	One time	1	Fixed	PROMIS B	1	CAT	Participant
19	Adult	2	One time	1	Fixed	PROMIS B	3	CAT	Participant
20	Adult	2	One time	1	Fixed	Happiness	3	Branch	Participant
21	Adult	2	One time	Not Included		Neuro-QOL Bank v1.0 - Anxiety			
22									

*If you approve of the settings for your study, click in the box below “Approve” on the Preview page*

- ▶ Step 2 is to click on “Preview Study”
  - Your study will now be launched for preview. Depending on the size of your study, this could take a few moments to over an hour.



*Once it reaches “100%” you can click on “Continue”*

- ▶ Clicking on continue will take you to the login screen.

*It is not recommended to click on “Start”.*

*The Login and Password is NOT your login and password for AssessmentCenter.net*

Welcome to Your\_Study

If you already have a Login and Password, please enter them in the boxes.

Login

Password

If you are a first time user, click Start below.

[Start](#)

Instead, return to AssessmentCenter.net and log in

## 14.1 Previewing Other Time Intervals

You can also preview the other time intervals without having to wait.

- ▶ Start by going back to the Administration tab
- ▶ Click on “Participant List”

### Study Overview

Study: Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	1	0	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

[Find/create Login](#)

[NIH Inclusion Enrollment Report](#)  
[Data Dictionary Report](#)  
[Enrollment Report](#)

To view a list of participants in this study, click the Participant List button below.

[Participant List](#)

- ▶ In the popup window, find the participant whose assessment schedule you

Study Arm:

Schedule:

Date Approach:

Site:

Login: (optional)

☒ Create participant login

\*\* Password:

Study code:

Baseline:

\*\* Consent: ☒ Yes ☐ No ☐ Test ☐ Preview

[View Schedule Details](#)

## Study Participants - Web Access





Participant	Login	Password	Stcode	Site
<u>zzz-{Missing}, {Missing}</u>	Preview1	2222	6001	Internet

[Close Window]

want to alter.

- ▶ Click on the “zzz-{Missing}, {Missing}” link
- ▶ Click on ‘View Schedule Details’ to bring up the participant’s schedule.

## Participant Schedule

Scheduled Event	Mode of Access	Start Date	End Date
 Assessment (1)	Clinician View	06/28/2013	07/03/2013
 Assessment (1)	Participant View	06/28/2013	07/03/2013
 Assessment (2)	<u>Clinician View</u>	12/15/2013	01/24/2014
 Assessment (2)	<u>Participant View</u>	12/15/2013	01/24/2014

- ▶ The participant’s schedule is now displayed in a popup window
  1. Find the assessment number you want to alter. Notice that there is a row for “Clinician View” and for “Participant View” – you must change the date for BOTH rows, ONE at a time.
  2. After the date is entered, click on the pencil for that row.
  3. Click on “close window”, then click on “Register Participant”.
  4. Reopen the window to ensure the change took effect. If not, re-enter the change to each row, ONE at a time.

*If you set two or more of the assessments to the same day, they will be back-to-back in the preview with a “welcome screen” before the first and a “thank you screen” after the last. There will be no other separators between intervals*

Studies Instruments Set-up Preview Administration

Overview **Registration Details** Participant Details Contact Information Custom Fields Reports Participant Data

Study Arm: Child

Schedule: Default [View Schedule Details](#)

Date Approach: 6/26/2013

Site: Internet

Login: (optional) Preview1 ☒ Create participant login

\*\* Password: 2222

Study code: 6001

Baseline:

\*\* Consent: ☒ Yes ☐ No ☐ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language: English

The registered participant can access their study at:

[https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your_Study&locale=en-US)

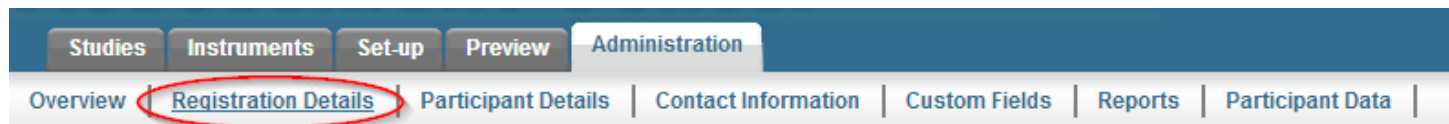
Copy & Paste the URL at the bottom of the registration details screen into the address bar of your web browser to begin the preview

- Creating and setting up studies
- Completing instruments not “seen by participant” (e.g., medical record abstractions)
- Registering participants for the study
- Accessing study data

- Use login and password created at time of registration
- Used to complete the assessments
  - NO access to data
- Cannot alter or change registration information

## 15.0 THE TWO SIDES OF ASSESSMENT CENTER

### 16.0 REGISTERING A “PREVIEW” PARTICIPANT



1. After you have logged back in to Assessment Center, go to the Administration Tab.

2. Click on “Find / create Login

**Assessment Center**

Studies Instruments Set-up Preview **Administration**

[Overview](#) | [Registration Details](#) | [Participant Details](#) | [Contact Information](#) | [Custom Fields](#) | [Reports](#)

### Study Overview

**Study:** Your\_Study

Goal	Participants	Accessed	Study Registered	Started	Completed	Off Study	Refusal
25	0	0	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

3. Select the Study Arm

*\*Login is optional. If left blank, Assessment Center will create one for you*

4. Select Consent status

## 5. Click on “Register Participant”

---

Study Arm: Child

Schedule: Default [View Schedule Details](#)

Date Approach: 6/26/2013

Site: Internet

Login: (optional) Preview1 ☒ Create participant login

\*\* Password: 2222

Study code: 6001

Baseline:

\*\* Consent: ☒ Yes ☐ No ☐ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language: English

The registered participant can access their study at:  
[https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your_Study&locale=en-US)

[Register Participant](#)

► After registration, a URL will appear at the bottom of the page.

1. Take note of the login and password

2. Copy & Paste this into your web browser when you are ready to preview the study.

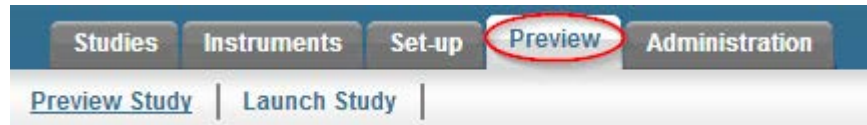
*\*The URL will automatically log in the preview participant.*

► Perform quality assurance as you go through the study.

---

## 17.0 APPROVING THE STUDY





- ▶ If your study is ready to be launched, go back to the Preview tab.
- ▶ Ensure that you approve of both of the Excel Export and the full preview.

led during      Yes      No  
☒      ☐

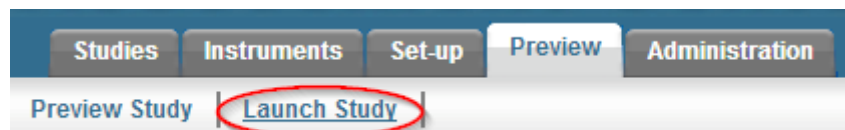
**Approve**

ow) and avigate ameters,	<input type="button" value="Export"/>	<input checked="" type="checkbox"/> 6/26/2013
avigate study in its	<input type="button" value="Preview Study"/>	<input checked="" type="checkbox"/> 6/26/2013

- ▶ Click on each box to approve.

---

## 18.0 LAUNCHING THE STUDY



1. Launch your study by clicking on “Launch Study” on the Preview tab.
2. Review endorsements of terms of use

**Launch Study**

The Launch Study page allows you to

- Endorse Terms & Conditions
- Launch your study for data collection

**TERMS & CONDITIONS**

Please click on the © symbol to read and endorse the Terms & Conditions. If you do not see a study name with a corresponding © symbol, the study does not have Terms & Conditions to approve. You must agree to an instrument's Terms & Conditions before Launching a study.

[PROMIS ©](#) Endorsed 06/21/2013

[Neuro-QOL ©](#) Not Endorsed

**LAUNCH STUDY**

**WARNING!** Launching a study locks items and instruments. You will **NOT** be able to revise this study after launch. Use the **PREVIEW STUDY** feature on this page BEFORE launching!

Launch Study

3. Read the warning about the study being locked once it is launched.
  4. Click “Launch Study” button if you are ready
- Your study has now been launched. The URL for your study will be displayed on this page.

Launch (Your\_Study)

**Launch Study**

- Your study has been launched. Your study can be accessed at the following link [https://www.assessmentcenter.net/ac1/Assessments/Your\\_Study](https://www.assessmentcenter.net/ac1/Assessments/Your_Study)
- If you would like to bookmark the participant login screen, click this [Add to Favorites](#) link.

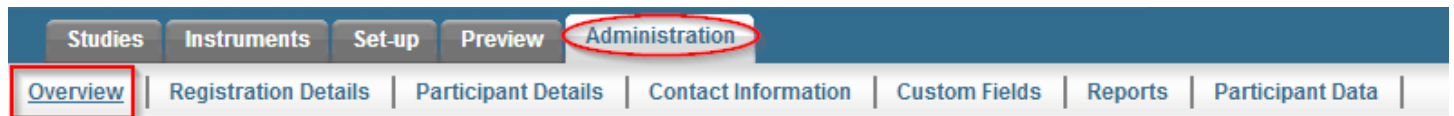
The Launch Study page allows you to

- Endorse Terms & Conditions
- Launch your study for data collection

---

## 19.0 CLEARING PRACTICE DATA

- You may want to clear all of the practice data before any real participants complete assessments
- Assessment Center will not delete data, but can classify practice data as “test” participants.



1. Go to the Overview subsection of the Administration tab
2. Then find a practice participant by clicking on the “Participant List”
3. Click on the practice participant in the “Study Participants” popup window.

To view a list of participants in this study, click the Participant List button below.

[Participant List](#)

### Study Participants - web Access

Participant	Login	Password	Stcode	Site
zzz-{Missing}, {Missing}	P0001	ABC	6002	Internet
zzz-{Missing}, {Missing}	Preview1	2222	6001	Internet

[\[Close Window\]](#)

4. Change the participant’s consent to “Test”.

Study Arm:

Schedule:   [View Schedule Details](#)

Date Approach:

Site:

Login: (optional)  ☒ [Create participant login](#)

\*\* Password:

Study code:

Baseline:

**\*\* Consent:** ☐ Yes ☐ No ☒ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language:

5. To save this change, click on “Register Participant”

- This participant will no longer appear on the Participant List.
- Repeat these steps until all test participants have been removed

*In the data export, these test participants will appear as Consent=3*

---

## 20.0 PARTICIPANT REGISTRATION

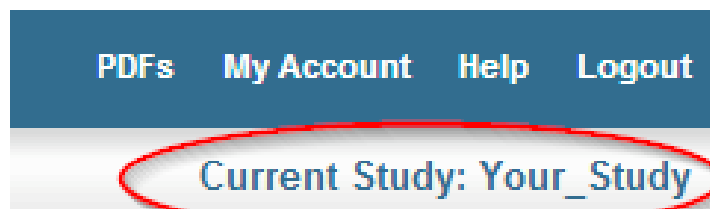
For some studies, you may want to register participants through the administrative side of the site [for example, if you want to manually select study arms or create specific Logins or Passwords]

Otherwise, the Registration process will be included automatically when a participant (or data collector on behalf of a participant) access the administrative side of the site.

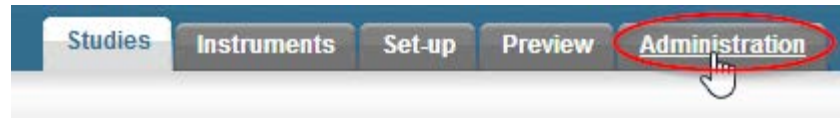
### 20.0.1 PARTICIPANT REGISTRATION

To begin manual participant registration, go to <https://www.assessmentcenter.net> and login with YOUR login and password.

1. Check to make sure that the study you want to register participants into is the current study by looking at the top right of the screen. If it is not the current study, click the name of your study in the list of studies.



2. The next step is to click on the Administration tab



3. Then click on the “Find/create Login button

► On the registration screen you will:

#### Study Overview

**Study:** Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25		0		1	1	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

# 1. Select the Study Arm and Schedule

The screenshot shows a registration form with several sections highlighted by red boxes:

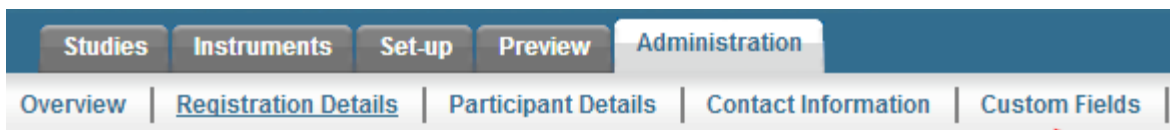
- Study Arm and Schedule:** Includes dropdowns for "Study Arm:" (set to "Child") and "Schedule:" (set to "Default"), a "View Schedule Details" link, a "Date Approach:" field (7/3/2013), and a "Site:" dropdown (Internet).
- Login and Password:** Includes a "Login: (optional)" field, a checkbox for "Create participant login", a "\*\* Password:" field, a "Study code:" field, and a "Baseline:" field.
- Consent:** Includes a "\*\* Consent:" section with radio buttons for "Yes", "No", "Test", and "Preview".

Below these sections are fields for "Non-Enrollment Reason:", "Off Study:", and "Language:" (set to "English").

2. Create Login – Assessment Center will randomly generate this. If you want to make your own, click the box next to “Create Participant Login”. Creating the login may be helpful for multi-site studies to allow for easier tracking.

3. Choose a password

4. Indicate if the participant has consented.

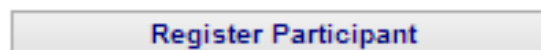


*If your study collects demographics, contact information, or other information, DO NOT click on “Register Participant, yet.*

- ▶ To continue entering registration information about the participant, click on the sub sections at the top of the page.
- ▶ Remember that some of the fields can be considered Protected Health Information (PHI) under HIPAA. DO NOT enter this information unless your IRB has approved it being stored on Assessment Center.

*\*PHI includes: name, date of birth, geographic location smaller than state, email address, and others.*

- ▶ After you have completed entering registration information, return to the “Registration Details” subsection and click on “Register Participant”.



- ▶ At the bottom of the “Registration Details” page is the custom URL for that participant.
- ▶ Navigating to this URL takes the participant directly into the assessment. No login / password required as it is already part of the URL.

- If the participant is completing the assessment later or from another computer, he/she would use the study URL and his/her login/password.

Study Arm: Child

Schedule: Default [View Schedule Details](#)

Date Approach: 7/3/2013

Site: Internet

Login: (optional) P0001 ☒ Create participant login

\*\* Password: ABC

Study code: 6002

Baseline:

\*\* Consent: ☒ Yes ☐ No ☐ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language: English

The registered participant can access their study at:  
[https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=P0001&txtPWD2=ABC&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=P0001&txtPWD2=ABC&Action=autologin&Study=Your_Study&locale=en-US)

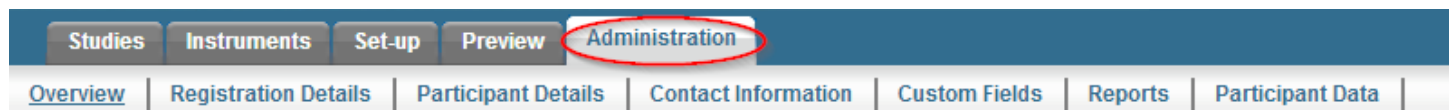
[Register Participant](#)

---

## 21.0 ADMINISTRATIVE ASSESSMENTS

- If your study has assessments that are completed by the study team, such as medical record abstraction, recording of test scores, etc., return to <https://www.assessmentcenter.net> and log in





- Go to the Administration tab
- Administrative Assessments

After clicking on the Administration tab, you should be in the “Overview”

### Study Overview

Study: Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	2	1	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

To view a list of participants in this study, click the Participant List button below.

[NIH Inclusion Enrollment Report](#)  
[Data Dictionary Report](#)  
[Enrollment Report](#)

subsection. Here you will click on “Participant List”

- Click on the participant.

### Study Participants - Web Access

Participant	Login	Password	Stcode	Site
<u>zzz-{Missing}</u>	<u>{Missing}</u>	P0001 ABC	6002	Internet

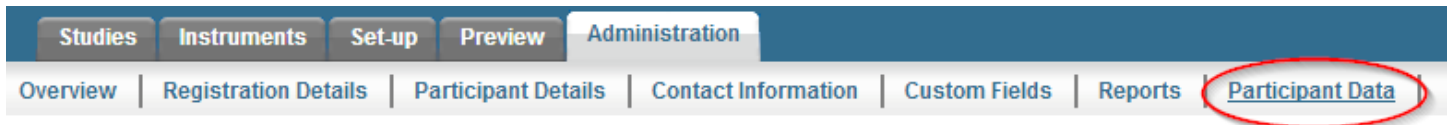


[\[Close Window\]](#)

\*If you have filled in a name, it will be displayed in place of the “zzz...”

- ▶ This screen displays the Assessments for the participant and the responses.
- ▶ Names of completed instruments will be crossed out.

► To select an instrument, click its name



*\*As you enter the data into these Administrative assessments, you should click on Save often.*

Scheduled Events  
**Assessment (1)**  
1Form(s)  
PROMIS Bank v1.0 - Anger  
Happiness Rating Scale  
PROMIS Bank v1.0 – Applied Cog General Concerns  
**Assessment (2)**

Login: P0001

**In the past 7 days**

**When I was frustrated, I let it show**

- ☐ 1 - Never
- ☐ 2 - Rarely
- ☐ 3 - Sometimes
- ☐ 4 - Often
- ☐ 5 - Always

**In the past 7 days**

**I was irritated more than people knew**

- ☐ 1 - Never
- ☐ 2 - Rarely
- ☐ 3 - Sometimes
- ☐ 4 - Often
- ☐ 5 - Always

Save

*If your Assessment Center session times out, unsaved data will be lost.*

Save

**FREQUENTLY!**

## APPENDIX G



1

# BADER CONSORTIUM

## REHABILITATION OUTCOMES MEASUREMENT CORE

### Patient Reported Outcomes Assessment Training Manual

DRAFT 03 JUL 2013

## Benefits of using Assessment Center

2

- ▶ Assessment Center is a free to use online platform for assessment creation, development, and administration.
- ▶ Assessment Center is HIPAA compliant and utilizes high security standards to ensure the study data remains secure. The study administrator controls permissions for users – users will only have access to what they are allowed to access.
- ▶ The ability to add any assessment instrument to the study allows you to use similar measures side-by-side. This would allow for the comparison of the results from a measure that you have used in the past with a new measure, as well as comparing results from short forms versus CATs.

## About this Training Manual

- ▶ This guide is intended as a supplement to the Assessment Center manual.
- ▶ The manual can be found on <https://www.assessmentcenter.net>
  - ▶ On the left side of the page is a list of helpful resources that includes user manuals.
- ▶ Notice the 3 different ways to contact Assessment Center for help.
  - ▶ When contacting Assessment Center about a problem with your study, please be as specific as you can with details such as study name, instrument name and item ID.

### Resources

[Instrument Library](#)  
[Scoring Manuals](#)  
[Workshops](#)  
[Publications](#)  
[Presentations](#)  
[User Manuals](#)  
[Glossary](#)  
[Terms and Conditions](#)  
[FAQ](#)  
[Release History](#)  
 Usage Statistics  
[About Us](#)  
[Video Tutorials](#)

Contact Us  
[help@assessmentcenter.net](mailto:help@assessmentcenter.net)  
 Help Line: 877-283-0596

3

## User Registration

- ▶ Before you begin working with Assessment Center, you will need to register.
- ▶ Go to <https://www.assessmentcenter.net>

Login  
 Password  
 Continue  
 Register New User  
 Forgot Password

- ▶ Click on "Register New User" in the top right of the screen
- ▶ If you have already registered, but forgotten your password, click on "Forgot Password".

4



## User Registration – Step 1

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- ▶ Step 1 of the registration process includes creating a login and password
- ▶ Choosing a strong password at this point is a critical step in keeping your study secure.
- ▶ It is required to be at least 6 characters.
- ▶ A strong password would be 8 or more characters and include upper & lowercase, numbers, and special characters (e.g., # \$ @)

**Registration step 1: Please complete fields below.**

Save Cancel

Login\*

Password\*

Re-enter Password\*

Title

First Name\*

Last Name\*

Institution\*

Email\*

Re-enter Email\*

Phone

Mailing Address

City

State/Province

Country

Postal Code

(\*) fields are required.

## User Registration – Terms & Conditions

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- ▶ You will be required to read and accept the Assessment Center terms & conditions.

**Assessment Center**

**ASSESSMENT CENTER TERMS AND CONDITIONS**

Last Updated 1/21/2011

**R**You understand and agree that the services that Northwestern University - Department of Medical Social Sciences (NU-MSS) provides to you through the Assessment Center websites are subject to the following Terms and Conditions (TAC). NU-MSS reserves the right to update the TAC at any time. Changes in the TAC will apply to new users and to new projects created by existing users after these changes are posted. The most current version of the TAC can be reviewed by clicking on the "Terms and Conditions" hypertext link located on the Assessment Center Home page.

**DESCRIPTION OF SERVICES.**

Assessment Center provides you with access to a variety of resources, including survey measures, study administration, data management, and storage of statistical analysis results (collectively, the "Services"). The Services, including any updates, enhancements, and/or new features are subject to the TAC, and your use of the Services constitutes acceptance of all terms and conditions set forth in the TAC.

**PRIVACY AND PROTECTION OF PERSONAL INFORMATION.**

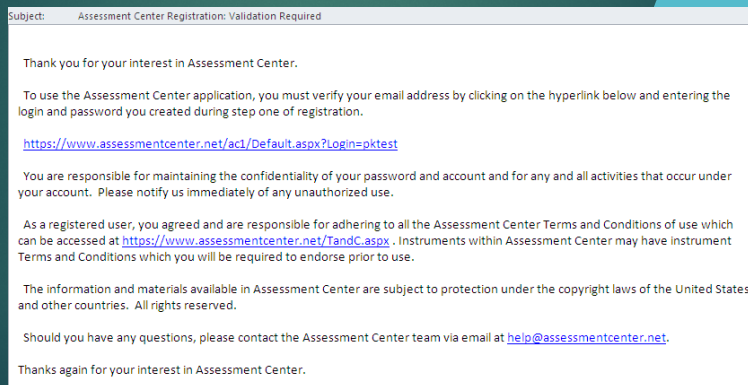
Accept Cancel

Mailing Address

## User Registration – Step 2

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- After accepting the terms & conditions, an email will be sent to the email address you registered with. Follow those instructions to activate your account



## User Registration – Step 3

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- The link in the email will take you to a special login screen. Here is where you will enter the login and password you used to register.

**Welcome to Assessment Center<sup>SM</sup>**

Please enter your User ID and Password below to access the center.

When you enter the site, the study information you provided at registration will automatically be included in your studies list.

You may begin work on this study immediately or create an additional study.

- Registration Step 3: Your registration is almost complete. To complete your registration, please enter the login and password you created during registration step 1 in the fields below and click Continue.

User ID:

Password:

[Forgot Password](#)

If at any time you have any questions or difficulties, please contact the Center Administrators by email to [help@assessmentcenter.net](mailto:help@assessmentcenter.net)



## Navigating Assessment Center

9

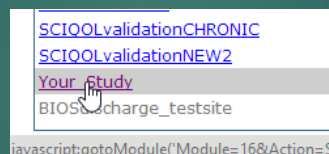
- ▶ Assessment Center's functions are split up into 5 tabs.
- ▶ The next set of slides will give a brief overview of each tab
- ▶ Step-by-step instructions will follow the overview



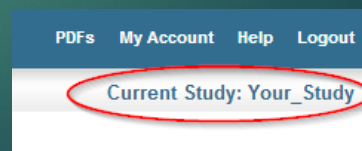
## Studies Tab

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- ▶ The Studies tab contains a list of all the studies you are a part of.
- ▶ The study that is currently selected will be at the top of the list. To select a study, click on the title of the study.



- ▶ The currently selected study will also be displayed at the top right of the screen



## Instruments Tab

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- ▶ The Instruments tab shows the list of instruments in your study.
- ▶ From this page you can also add, create, and edit instruments.

Study Content (Your\_Study)

**Study Content**

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Order	Name	Administration Study	Include	Notes	Terms of Use
1	<input type="text"/> PROMIS Bank v1.0 - Anger	PROMIS	<input checked="" type="checkbox"/>	Notes	
3	<input type="text"/> <a href="#">Happiness Rating Scale</a>	Your_Study	<input checked="" type="checkbox"/>	Notes	
3	<input type="text"/> PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS	<input checked="" type="checkbox"/>	Notes	

## Instruments Tab

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- ▶ The Instruments tab also has a "breadcrumb trail" that makes finding your location easy.
- ▶ It is located at the top of the page

Studies Instruments Set-up Preview Administration

[Study Content \(Your Study\)](#) >> [Instrument Detail \(Happiness Rating Scale\)](#) >> Item Details (happiness\_2)

**Item Detail**

- ▶ It shows your current location and allows you to quickly move up levels (e.g., from Item Details to Instrument Detail) by clicking where you would like to navigate.

## Set-up Tab

13

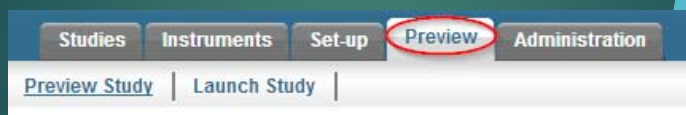


- ▶ The Set-up tab has five subsections that allow you to customize the way the study functions as well as the consent and registration process

## Preview Tab

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- ▶ The Preview tab is the tab that allows you to review the study to ensure it has all of the content and functions properly



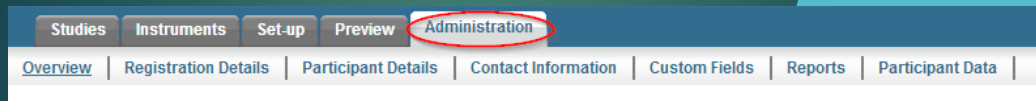
- ▶ When the study is ready, you will move on to the "Launch Study" section
- ▶ Once a study is launched, it cannot be edited



# Administration tab

15

- ▶ This tab has functions for before and after launch of the study.



## Before Launch

- ▶ Create "test" participants
- ▶ View and alter "test" participants' schedule of assessments

## After Launch

- ▶ Register participants
- ▶ Download data
- ▶ Download reports such as data dictionary
- ▶ Review progress and other statistics about the study
- ▶ Modify participants' assessment schedules

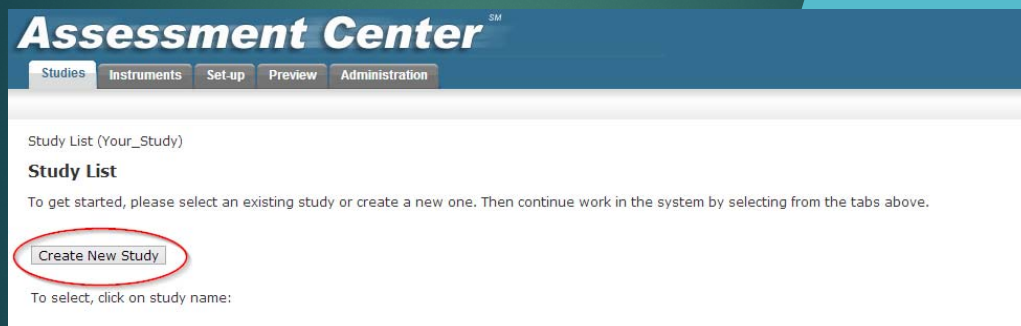
# Creating a study on Assessment Center

16



A study can be created in two steps

Step 1: on the "Studies" tab click on "Create New Study."



## Creating a new study

17

Step 2: fill in the name of the study, and a brief description.  
Then click "Save".

Study List (Your Study) >> Study Properties

### Study Properties

Name of Study\*  Save Back

Description\*

Study Status\* ☒ Active ☐ Archived

(\*) fields are required.

## Adding instruments to your study

18



- ▶ Now that your study is created, the next step is to add instruments.
- ▶ There are a number of publicly available studies / instruments that can be added to your study.
- ▶ You can also create your own instruments or add instruments that are not publicly available on Assessment Center.

### Instruments Available on Assessment Center

#### Publicly Available

- ▶ PROMIS
- ▶ NeuroQOL

#### By Request

- ▶ SCI-QOL
- ▶ TBI-QOL

## Adding Instruments to your study

19

The first step in creating or adding an instrument is found in the "Instruments" tab. Here you see options for adding and creating instruments.

To add an instrument, click "Add".

Study Content (Your\_Study)

**Study Content**

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Order	Name	Administration Study	Include	Terms of Use
<b>PDF</b> <b>REVIEW</b>				

## Adding PROMIS instruments to your study

20

Study Content (Your\_Study) >> Add an Instrument

**Add an Instrument**

First, select instrument or battery (a fixed set of instruments). Use search criteria to find and add instruments / batteries to your study.

☒ Instrument  
☐ Battery

Study: PROMIS 1
 Type: All
 Domain: All
2 Show Results

Search Results

To add a PROMIS instrument to your study follow these steps:

- 1) In the "Study:" box, select "PROMIS"
- 2) Click on "Show Results"



## Adding PROMIS instruments to your study

21

Select	Name	Administration Study	Type	Domain	Statistics	Terms of Use
<input checked="" type="checkbox"/>	PROMIS Bank v1.0 - Anger	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Emotional Distress/Negative Affect, Anger	<a href="#">Statistics</a>	©
<input type="checkbox"/>	PROMIS Bank v1.0 - Anxiety	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Emotional Distress/Negative Affect, Anxiety/Fear	<a href="#">Statistics</a>	©
<input type="checkbox"/>	PROMIS Bank v1.0 - Applied Cog Abilities	PROMIS	Item Bank/CAT (Computerized Adaptive Testing)	Applied Cognition, Abilities	<a href="#">Statistics</a>	©

Now, you will be presented with a list of available PROMIS instruments.

- To explore the individual items of the instruments, click on the + symbol next to the instrument's name. This will expand the instrument so you can view the text of each item and the response choices.
- To select an instrument for your study, put a checkmark into the box for that instrument.
- You can review and accept the terms of use by clicking on the © symbol
- To add the instrument, click "Add to Study"

## Adding PROMIS instruments to your study

22

Click on the Instruments tab to see the instrument(s) that were added to your study.

Study Content (Your\_Study)

**Study Content**

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

You have selected the following instruments for this study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

Order	Name	Administration Study	Include	Terms of Use
1	PROMIS Bank v1.0 - Anger	PROMIS	<input checked="" type="checkbox"/>	©

## Creating an instrument



23

- ▶ The instruments you want to use for your study may not be available on Assessment Center. You can use the creation tools in Assessment Center to include those instruments into your study.
- ▶ User-created instruments can be used seamlessly with publicly available instruments.
- ▶ To begin, go to the "Study Content" page. Here you will click "Create"

Study Content (Your\_Study)

**Study Content**

Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.

Order the instruments by entering the desired position into the text box, then click Save.

To exclude an instrument from your study, click on the Include checkbox.

☒ Hide Excluded Instruments

**Study Content**

Order	Name	Administration Study	Include	Terms of Use

**Add Save Create**

## Creating individual items for an instrument

24

**Item Detail**

Save Cancel

ID\*: happiness\_1 *must be unique across all Assessment Center studies*

Domain\*

- Ability to Participate in Social Roles/Activities
- Satisfaction with Social Roles and Activities
- Satisfaction with Discretionary Social Activities
- Satisfaction with Social Roles
- Social Isolation
- Social Relationships
- Stigma
- Stress
- Urinary/Bladder Function
- Other

Item Contains

Protected ☐

Health Information (PHI) ☐

Context

When you first woke up...  
 These insert line breaks. Other HTML formatting available are <i></i> for italics and <u></u> for underlining.

Stem\*

How happy were you this morning?

Administration Your\_Study Original Instrument: Happiness Rating Scale Creation Date: 6/21/2013

Show Item History

**Responses**

Type: Multiple Choice

Score	Response Text	Show Response Score
1	Very Unhappy	<input type="checkbox"/> Delete
2	Somewhat Unhappy	<input type="checkbox"/> Delete
3	Somewhat Happy	<input type="checkbox"/> Delete
4	Very Happy	<input type="checkbox"/> Delete

Move response up or down



## Creating individual items for an instrument

25

- ▶ Assessment Center allows for 3 types of HTML code to be used when creating individual items.

  1. line breaks are created by adding in `<br>` where you want a line break. A good separation for context and stem is three line breaks (`<br><br><br>`).
  2. Underlining is accomplished by putting `<u>` & `</u>` on either side of the text you want underlined (In the last `<u>month</u>`). The `" / "` character ends the code.
  3. Italics is done similarly to underlining. The code is `<i>` & `</i>`.

In the example, you will see the code and resulting item from the code with and without the line breaks

Context
In the last <code>&lt;u&gt;month&lt;/u&gt;&lt;br&gt;&lt;br&gt;&lt;br&gt;</code>
Stem*
<code>&lt;i&gt;have you been happy?&lt;/i&gt;</code>

In the last <u>month</u>
<i>have you been happy?</i>
<input type="radio"/> Yes
<input type="radio"/> No

In the last <u>month</u>
<i>have you been happy?</i>
<input type="radio"/> Yes
<input type="radio"/> No

## Creating individual items for an instrument

26

- ▶ After you have finished creating an item and clicking "Save", A popup window will appear for you to enter any notes about the item.
- ▶ For new items, comments are not required.
- ▶ For edited items, you must select an Item History Category and enter at least one character into the Comments box.
- ▶ Click Save when you are done

**Assessment Center**

Item History Category\* New Item Date\* 6/21/2013

Comments/Reasons for Changes\*

Save Cancel

## Copying individual items for an instrument

27

- ▶ Many instruments will have items with the same response options or context. Assessment Center allows you to copy an item by clicking on "Copy"

The screenshot shows the 'Responses' section of the Assessment Center interface. At the top, there are buttons: 'New', 'Copy', 'Statistics', 'Save', and 'Cancel'. The 'Copy' button is circled in red. Below the buttons, there is a dropdown menu for 'Type' set to 'Multiple Choice' and an 'Add another row' button. A table with two columns, 'Score' and 'Response Text', is visible. The 'Score' column has two rows with scores 1 and 2, and arrows for reordering. The 'Response Text' column has two rows: 'Very Unhappy' and 'Somewhat Unhappy'. To the right of the table, there is a 'Show Response Score' checkbox and two 'Delete' links.

- ▶ This copied item will be identical to the original item except you must provide an unique item ID

## Changing the order of individual items

28

- ▶ The Instrument Detail Screen is reached by clicking on the name of an instrument
- ▶ Here you can edit the order of the items.
- ▶ When you have finished ordering, click "Save"

\*Assessment Center will timeout after 5 minutes of inactivity. Keep this in mind when re-ordering items. If you timeout, your progress will not be saved.

\*it can be helpful for instruments that are a "work in progress" to group the items as shown in the example. This makes it easier to add an item to a section without having to renumber all of the items (e.g., adding in an item at #2 and having to renumber items 2-200)

The screenshot shows a list of items in the Instrument Detail Screen. The items are numbered 118 through 205. Item 119 is circled in red. The items are grouped into sections: 'MRA outside procedures2', 'MRA outside procedures3', and 'MRA outside OR1' through 'MRA outside OR6'.

Item ID	Item Name
118	MRA outside procedures2
119	MRA outside procedures3
200	MRA outside OR1
201	MRA outside OR2
202	MRA outside OR3
203	MRA outside OR4
204	MRA outside OR5
205	MRA outside OR6

## Customizing instruments

29

- ▶ On the study content page, there are options for customizing, previewing, and editing the properties of instruments.

Study Content						
Order	Name	Administration Study				
1	PROMIS Bank v1.0 - Anger	PROMIS	<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>
2	PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS	<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>
3	Happiness Rating Scale	Your_Study	<a href="#">Customize</a>	<a href="#">Preview</a>	<a href="#">Properties</a>	<a href="#">Statistics</a>

- ▶ The next step is setting up the instrument so it functions properly
- ▶ Click on "Customize"

## Creating an instrument

30

Study Content (Your\_Study) >> Instrument Properties

### Instrument Properties

Name\* Happiness Rating Scale Save Back

Select the domain or domains for this instrument\*

- Ability to Participate in Social Roles/Activities
- Satisfaction with Social Roles and Activities
- Satisfaction with Discretionary Social Activities
- Satisfaction with Social Roles
- Social Isolation
- Social Relationships
- Stigma
- Stress
- Urinary/Bladder Function
- Other

Language: English

Status: Under Development

Type\*: Item Bank/CAT (Computerized Adaptive Testing)

IRT Model: Short Form

Description\* A Scale for rating participant's happiness

Comments

- ▶ The name must be unique in Assessment Center
- ▶ Select the appropriate domain that describes the instrument
- ▶ Enter a brief description
- ▶ Choose "under development"
- ▶ Choose the type of instrument [For nearly all purposes this will be "Short Form"]
- ▶ Click "Save"



## Customizing instruments

31

[Study Content \(Your Study\)](#) >> Instrument Customization

**Instrument Customization**

Instrument: Happiness Rating Scale

Administration Method: Sequential ▼ Set IRT Parameters

Instrument order is Sequential. Define blocks and template criteria below.

☐ Randomize Item Blocks ☐ Randomize Items within Item Blocks

- ▶ In the top left of the screen are the "Administration Method" options.
- ▶ The options are Sequential [in order], Random, and Branch.
- ▶ If your instrument has specific IRT Parameters, or if you'd like to modify the IRT parameters [e.g., min/max # of items, max standard error] for an existing item bank/CAT, those settings are accessed by clicking on "Set IRT Parameters"

## Customizing instruments

32

- ▶ The appearance of the items can also be customized.
- ▶ All items can be changed to have one template or the template for each individual item can be set.
- ▶ Items can be set to "Auto Advance" – once an response is chosen, that response is saved and the next item is displayed

Templates determine how an item will appear to study respondents on the data collection screens.

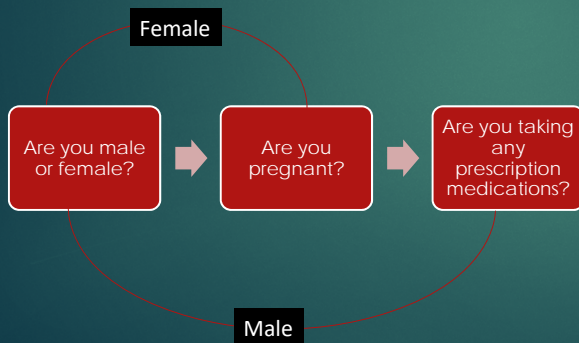
Change all item templates to: Please select ▼

Then Go To	Template
<span>Please Select ▼</span>	<span>Vertical 01 ▼</span>
<span>Please Select ▼</span>	<span>Vertical 01 ▼</span>

## Customizing instruments

33

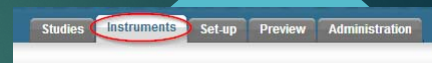
- ▶ Choosing Branch as the administration method allows you to set skip logic for the instrument.
- ▶ When certain criteria are met, an item or items are skipped. This is helpful in instances where some responses require more information or do not apply to the participant (e.g., female-related items skipped for male participants).
- ▶ The branching function only works by skipping the next item or set of items. For example, A screener question at the beginning cannot be set to skip items at the end of the instrument.



## Item-level Quality Assurance

34

- ▶ It is highly recommended that you preview each instrument to ensure that it functions how you want it to function.
- ▶ Once a study is launched, it is not possible to change the instruments.



Study Content			
Order	Name	Administration Study	
1	PROMIS Bank v1.0 - Anger	PROMIS	<a href="#">Customize</a> <a href="#">Preview</a>
2	PROMIS Bank v1.0 - Applied Cog General Concerns	PROMIS	<a href="#">Customize</a> <a href="#">Preview</a>
3	<a href="#">Happiness Rating Scale</a>	Your_Study	<a href="#">Customize</a> <a href="#">Preview</a>

## Item-level Quality Assurance

35

- ▶ There are two options for previewing and it is recommended to do both of them.

☒ Preview item list  
☐ Simulate instrument administration with customized settings  
☐ Show Execution Detail (e.g. Item ID and Ability Estimate)  
 Language: English ▼  
Continue Cancel

## Item-level Quality Assurance

36

- ▶ The first option is to preview the item list.
  - ▶ Best for checking for typos and other errors when the individual items were entered.
- ▶ This view displays all of the items in one list.

**Assessment Center**

**[happiness\_1]**  
**When you first woke up...**  
**How happy were you this morning?**

☐ Very Unhappy  
☐ Somewhat Unhappy  
☐ Somewhat Happy  
☐ Very Happy

**[happiness\_2]**  
**When you first woke up...**  
**How rested did you feel?**

☐ Very tired  
☐ Somewhat tired  
☐ Somewhat rested  
☐ Well rested



## Item-level Quality Assurance

37

- ▶ The second type of preview is a simulation of what the participant would see.

https://www.assessmentcenter.net/ac1/Modules/PreviewInstrumentOptions.aspx?InstrumentID=2e16caae0e0c4749b4d21578ef2f4fc58&Type=ShortForm

**View Options**

☐ Preview item list  
☒ Simulate instrument administration with customized settings  
☐ Show Execution Detail (e.g. Item ID and Ability Estimate)

Language: English

Continue Cancel

## Quality Assurance

38

- ▶ The simulation option also allows you to:
- ▶ Test-drive instrument customization settings such as IRT, branching, and randomization.
- ▶ Only the area inside the box is displayed in live studies.

When you first woke up...

How happy were you this morning?

☐ Very Unhappy  
☐ Somewhat Unhappy  
☐ Somewhat Happy  
☐ Very Happy

Previous Next Exit

The area inside the box is what is displayed during full previews and live studies

## Setting up your study



39

- ▶ The first step is to select the language. Currently only English and Spanish are available.
- ▶ This choice affects the language of the buttons on each page as well as screens set by Assessment Center.
- ▶ PROMIS measures that are available in Spanish will change to Spanish if you choose that as your language.
- ▶ User-created instruments and welcome screens are not affected.

## Setting up your study



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- ▶ Step 2 is Basic settings



## Setting up your study



41

- Step 3 is Advanced Study Setup

Advanced Study Setup (Your\_Study)

### Advanced Study Setup

Create at least one arm/assessment instance and click Save. You will then be able to click on the Specify Instruments link.

[New Row](#)

Arm	Assessment	Day Assessment Opens	Window	
<input type="text" value="Type arm name here"/>	<input type="text"/>	Day <input type="text"/>	<input type="text"/> Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>

- This is where the arms of the study, longitudinal intervals, and instruments for each arm/interval are set.

## Setting up your study

42

- Creating the Arms of your study
- Each arm MUST have a baseline
- The spelling of each set of Arms must be identical or Assessment Center will assume it is a new Arm
- Choose when the assessment windows opens and for how many days it will be open.

[New Row](#)

Arm	Assessment	Day Assessment Opens	Window	
Adult	1	Day 0	5 Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>
Adult	2	Day 170	40 Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>
Child	1	Day 0	5 Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>
Child	2	Day 170	40 Days	<a href="#">Specify Instruments</a> <a href="#">Delete</a>

In the example, Adult Arm 2 opens on Day 170 and is open for 40 days.

\*The windows for the arms do not have to be the same

## Setting up your study

43

- Specify instruments by clicking on "Specify Instruments" on the Advanced Study Setup Screen

[Advanced Study Setup \(Your Study\)](#) >> Specify Instruments

**Arm / Assessment Details**

Arm: Adult Assessment: 1 Save Back

Instruments can be blocked. These blocks can be administered randomly or in a fixed order. Instruments in the same block are administered together in a random or pre-defined order.

Instrument Block	Block Administration	Instrument	Order within Block	Completed by Participant	Administer
1	Fixed	PROMIS Bank v1.0 - Anger	1	<input checked="" type="checkbox"/>	CAT
1	Fixed	PROMIS Bank v1.0 - Applied Cog General Concerns	2	<input checked="" type="checkbox"/>	CAT

- The options available are:
  - Instrument Block and the order within the block
  - If the instrument is completed by the participant
  - Block Administration – the random option randomizes the order of the instruments, not the individual items of each instrument.
  - Any instruments added after you complete this will be a part of all arms and intervals. Simply navigate back to this page to reorder measures or exclude new measures from specific arms/intervals

## Setting up your study

44

- In the "Consent" page of the setup, you can copy and paste your informed consent documents.

Consent (Your Study)

**Consent Forms**

To add up to three consents forms to your study, expand applicable consent boxes and enter information.

**- Consent 1** Include

☐ Consent contains Protected Health Information (PHI)

☐ Include an endorsement checkbox

☐ Include an endorsement text entry

**- English**

Endorsement checkbox text: I accept

Endorsement text entry text: Please type in your name

Please copy and paste your consent form content into the box below.

Rich text editor toolbar with options for Bold, Italic, Underline, Font, Size, and other formatting tools.

Large text area for pasting consent form content.

## Setting up your study

45

- ▶ The registration section of setup is used to select which items you want to collect for your study.
- ▶ You can also create custom fields by using the choices on the right.

Registration (Your\_Study)

**Registration**

You may define participant registration forms below.

Custom Demographic Fields					Additional Custom Fields	
Include	Field Label	Required	Validation			
			Min Value	Max Value		
<input checked="" type="checkbox"/>	Age	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="+ Date Field"/>	
<input type="checkbox"/>	Date of Birth	<input type="checkbox"/>			<input type="button" value="+ Number Field"/>	
<input checked="" type="checkbox"/>	Gender	<input type="checkbox"/>			<input type="button" value="+ Number2 Field"/>	
<input checked="" type="checkbox"/>	Ethnicity	<input type="checkbox"/>			<input type="button" value="+ Text Field"/>	
<input checked="" type="checkbox"/>	Race	<input type="checkbox"/>			<input type="button" value="+ List Field"/>	
<input type="checkbox"/>	Doctor	<input type="checkbox"/>				
<input type="checkbox"/>	First Name	<input type="checkbox"/>				
<input type="checkbox"/>	Last Name	<input type="checkbox"/>				
<input type="checkbox"/>	Street	<input type="checkbox"/>				

## Previewing the Study

46

- ▶ The final step before launching the study is to do a full preview. This allows you to go through the registration, consent, and all instruments in the same way a live participant would.
- ▶ Logins and passwords can be created for those outside of the team developing the study to preview the "live" version of the study for feedback and quality assurance.
- ▶ There are 2 steps in the full preview of a study.

**Approve**

**REVIEW AND APPROVE YOUR STUDY CONFIGURATION\***

Assessment Center is currently in Beta testing. Please review your Study Setup Summary (below) and click the Export button for your Study Configuration Report. To apply changes to your study, navigate back to your study by using the tab above. If you need assistance in reviewing your study parameters, please contact [help@assessmentcenter.net](mailto:help@assessmentcenter.net)

**PREVIEW AND APPROVE YOUR STUDY\***

To preview your study, click on the Preview Study button. To apply changes to your study, navigate back to your study by using the links above. It is highly recommended that you preview your study in its entirety prior to launching for data collection.

Be sure to review your data exports on the Administration tab prior to launching your study.

☐

☐



## Previewing the Study

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The 1<sup>st</sup> step is to review the Excel preview of the study

- ▶ The Excel preview contains the information that was set in the "Advanced Study Setup" and instrument customization menus.
- ▶ If you approve of the settings for your study, click in the box below "Approve" on the Preview page

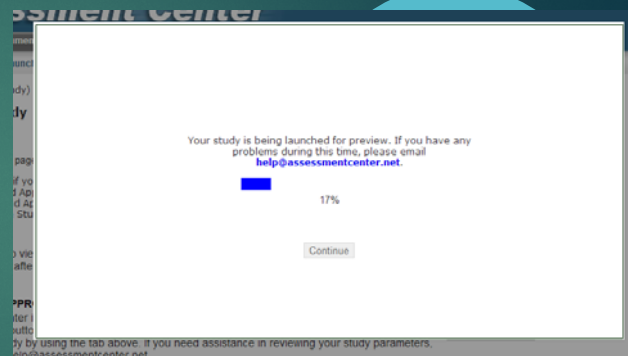
2	Study Name: Your_Study							
3	Report Generated: 6/26/2013 12:58:44 PM							
4								
5	Study Arm	Assessme	Schedule	Instrumer	Block Adm	Instrumer	Order wit/ Administr	Completed By
6	Child	1	One time	1	Fixed	PROMIS B	1 CAT	Participant
7	Child	1	One time	1	Fixed	PROMIS B	3 CAT	Participant
8	Child	1	One time	1	Fixed	Happines	3 Branch	Participant
9	Child	1	One time	Not Included			Neuro-QOL Bank v1.0 - Anxiety	
10	Child	2	One time	1	Fixed	PROMIS B	1 CAT	Participant
11	Child	2	One time	1	Fixed	PROMIS B	3 CAT	Participant
12	Child	2	One time	1	Fixed	Happines	3 Branch	Participant
13	Child	2	One time	Not Included			Neuro-QOL Bank v1.0 - Anxiety	
14	Adult	1	One time	1	Fixed	PROMIS B	1 CAT	Participant
15	Adult	1	One time	1	Fixed	PROMIS B	2 CAT	Participant
16	Adult	1	One time	2	Fixed	Happines	3 Branch	Participant
17	Adult	1	One time	Not Included			Neuro-QOL Bank v1.0 - Anxiety	
18	Adult	2	One time	1	Fixed	PROMIS B	1 CAT	Participant
19	Adult	2	One time	1	Fixed	PROMIS B	3 CAT	Participant
20	Adult	2	One time	1	Fixed	Happines	3 Branch	Participant
21	Adult	2	One time	Not Included			Neuro-QOL Bank v1.0 - Anxiety	
22								

## Previewing the Study

48

Step 2 is to click on "Preview Study"

- ▶ Your study will now be launched for preview. Depending on the size of your study, this could take a few moments to over an hour.
- ▶ Once it reaches "100%" you can click on "Continue"



## Previewing the Study

49

- ▶ Clicking on continue will take you to the login screen.
- ▶ It is not recommended to click on "Start".
- ▶ The Login and Password is NOT your login and password for AssessmentCenter.net
- ▶ Instead, return to AssessmentCenter.net and log in

Welcome to Your\_Study

If you already have a Login and Password, please enter them in the boxes.

Login

Password

If you are a first time user, click Start below.

[Start](#)

## Previewing Other Time Intervals

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Studies Instruments Set-up Preview **Administration**

[Overview](#) | [Registration Details](#) | [Participant Details](#) | [Contact Information](#) | [Custom Fields](#) | [Reports](#) | [Participant Data](#)

You can also preview the other time intervals without having to wait.

- ▶ Start by going back to the Administration tab
- ▶ Click on "Participant List"

**Study Overview**

Study: Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	1	0	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

[Find/create Login](#)

[NIH Inclusion Enrollment Report](#)  
[Data Dictionary Report](#)  
[Enrollment Report](#)

To view a list of participants in this study, click the Participant List button below.

[Participant List](#)

## Previewing Other Time Intervals

51

- ▶ In the popup window, find the participant whose assessment schedule you want to alter.
- ▶ Click on the "zzz-{Missing}, {Missing}" link
- ▶ This takes you to the registration details page
- ▶ Here you will click on "View Schedule Details"

**Study Participants - Web Access**

Participant	Login	Password	Stcode	Site
<a href="#">zzz-{Missing}, {Missing}</a>	Preview1	2222	6001	Internet

[\[Close Window\]](#)

---

Study Arm:  Schedule:  Date Approach:  Site:  Login: (optional)  Password:  Study code:  Baseline:  ☒ Create participant login

**\*\* Consent:** ☒ Yes ☐ No ☐ Test ☐ Preview

[View Schedule Details](#)

## Previewing Other Time Intervals

52

**Participant Schedule**

Scheduled Event	Mode of Access	Start Date	End Date
Assessment (1) - Participant View	Participant View	06/28/2013	07/03/2013
Assessment (1) - Participant View	Participant View	06/28/2013	07/03/2013
Assessment (2)	Clinician View	12/15/2013	01/24/2014
Assessment (2)	Participant View	12/15/2013	01/24/2014

- ▶ The participant's schedule is now displayed in a popup window
- ▶ Find the assessment number you want to alter. Notice that there is a row for "Clinician View" and for "Participant View" – you must change the date for BOTH rows, ONE at a time.
- ▶ After the date is entered, click on the pencil for that row.
- ▶ Click on "close window", then click on "Register Participant".
- ▶ Reopen the window to ensure the change took effect. If not, re-enter the change to each row, ONE at a time.
- ▶ If you set two or more of the assessments to the same day, they will be back-to-back in the preview with a "welcome screen" before the first and a "thank you screen" after the last. There will be no other separators between intervals



## Previewing Other Time Intervals

53

Study Arm:

Schedule:

Date Approach:

Site:

Login: (optional)  ☒ Create participant login

\*\* Password:

Study code:

Baseline:

\*\* Consent: ☒ Yes ☐ No ☐ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language:

The registered participant can access their study at:  
[https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/ac1/Action.aspx?Module=48&txtUID2=Preview1&txtPWD2=2222&Action=autologin&Study=Your_Study&locale=en-US)

- ▶ Copy & Paste the URL at the bottom of the registration details screen into the address bar of your web browser to begin the preview

## The two sides of Assessment Center

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Assessment Center has two distinct sides: The Administrative Side and the Participant Side. Here are the differences:

### Administrative Side

- ▶ Creating and setting up studies
- ▶ Completing instruments not "seen by participant" (e.g., medical record abstractions)
- ▶ Registering participants for the study
- ▶ Accessing study data

### Participant Side

- ▶ Use login and password created at time of registration
- ▶ Used to complete the assessments
- ▶ NO access to data
- ▶ Cannot alter or change registration information

## Registering a "preview" participant

55

**Assessment Center**

Studies Instruments Set-up Preview **Administration**

Overview Registration Details Participant Details Contact Information Custom Fields Reports

**Study Overview**

Study: Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	0	0	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

**Find/create Login**

- ▶ After you have logged back in to Assessment Center, go to the Administration Tab.
- ▶ Click on "Find / create Login"

## Registering for a full preview

56

Studies Instruments Set-up Preview **Administration**

Overview **Registration Details** Participant Details Contact Information Custom Fields Reports Participant Data

1. Select the Study Arm
2. Login is optional. If left blank, Assessment Center will create one for you
3. Select Consent status
4. Click on "Register Participant"

Study Arm: Child

Schedule: Default

Date Approach: 6/26/2013

Site: Internet

Login: (optional)

\*\* Password:

Study code:

Baseline:

\*\* Consent: ☐ Yes ☐ No ☐ Test ☐ Preview

Non-Enrollment Reason:

Off Study:

Language: English

**Register Participant**

For the preview, all that is required are the items marked with \*\*



## Registering for a full preview

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- ▶ After registration, a URL will appear at the bottom of the page.
- ▶ Take note of the login and password
- ▶ Copy & Paste this into your web browser when you are ready to preview the study.
- ▶ The URL will automatically log in the preview participant.
- ▶ Perform quality assurance as you go through the study.

Study Arm: Child  
 Schedule: Default  
 Date Approach: 6/26/2013  
 Site: Internet  
 Login: (optional) Preview 1  
 Password: 2222  
 Study code: 6001  
 Baseline:  
 Create participant login: ☒  
 Consent: ☒ Yes ☐ No ☐ Test ☐ Preview  
 Non-Enrollment Reason:  
 Off Study:  
 Language: English  
 The registered participant can access their study at:  
[https://www.assessmentcenter.net/act1/Action.aspx?Module=48&txtUID2=Preview1&txtPID2=2222&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/act1/Action.aspx?Module=48&txtUID2=Preview1&txtPID2=2222&Action=autologin&Study=Your_Study&locale=en-US)  
 Register Participant

## Approving the study

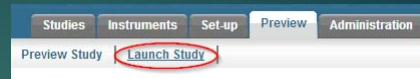
58

Studies Instruments Set-up **Preview** Administration  
 Preview Study | Launch Study

ed during Yes No  
 Approve  
 Export 6/26/2013  
 Preview Study 6/26/2013

- ▶ If your study is ready to be launched, go back to the Preview tab.
- ▶ Ensure that you approve of both of the Excel Export and the full preview.
- ▶ Click on each box to approve.

## Launching the Study



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- ▶ Launch your study by clicking on “Launch Study” on the Preview tab.
- ▶ Review endorsements of terms of use
- ▶ Read the warning about the study being locked once it is launched.
- ▶ Click “Launch Study” button if you are ready

Launch (Your\_Study)

### Launch Study

The Launch Study page allows you to

- Endorse Terms & Conditions
- Launch your study for data collection

**TERMS & CONDITIONS**  
Please click on the © symbol to read and endorse the Terms & Conditions. If you do not see a study name with a corresponding © symbol, the study does not have Terms & Conditions to approve. You must agree to an instrument's Terms & Conditions before Launching a study.

PROMIS © Endorsed 06/21/2013  
Neuro-QOL © Not Endorsed

**LAUNCH STUDY**  
**WARNING!** Launching a study locks items and instruments. You will **NOT** be able to revise this study after launch. Use the **PREVIEW STUDY** feature on this page **BEFORE** launching!

Launch Study

## Launching the Study

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- ▶ Your study has now been launched. The URL for your study will be displayed on this page.

Launch (Your\_Study)

### Launch Study

- Your study has been launched. Your study can be accessed at the following link [https://www.assessmentcenter.net/ac1/Assessments/Your\\_Study](https://www.assessmentcenter.net/ac1/Assessments/Your_Study)
- If you would like to bookmark the participant login screen, click this [Add to Favorites](#) link.

The Launch Study page allows you to

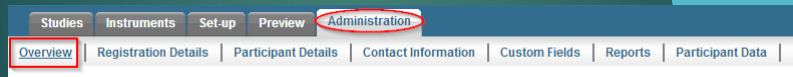
- Endorse Terms & Conditions
- Launch your study for data collection

- ▶ If the computer you are using will also be used by participants, you can click on the “Add to Favorites” link to make it easier to reach the login page.
- ▶ The link is how a participant accesses the study. Administrative access is still through <https://www.assessmentcenter.net>
- ▶ You may want to clear all of the practice data before any real participants complete assessments

## Clearing Practice Data

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- ▶ You may want to clear all of the practice data before any real participants complete assessments
- ▶ Assessment Center will not delete data, but can classify practice data as "test" participants.
- ▶ Go to the Overview subsection of the Administration tab



- ▶ Then find a practice participant by clicking on the "Participant List"

To view a list of participants in this study, click the Participant List button below.

[Participant List](#)

## Clearing Practice Data

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- ▶ Click on the practice participant in the "Study Participants" popup window.

Participant	Login	Password	Stcode	Site
zzz-{Missing}, {Missing}	P0001	ABC	6002	Internet
zzz-{Missing}, {Missing}	Preview1	2222	6001	Internet

[\[Close Window\]](#)



## Clearing Practice Data

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- ▶ Change the participant's consent to "Test".
- ▶ To save this change, click on "Register Participant"
- ▶ This participant will no longer appear on the Participant List.
- ▶ Repeat these steps until all test participants have been removed
- ▶ In the data export, these test participants will appear as Consent=3

The screenshot shows a participant registration form with the following fields and values:

- Study Arm: Child
- Schedule: Default
- Date Approach: 6/26/2013
- Site: Internet
- Login (optional): Preview1
- Password: 2222
- Study code: 6001
- Baseline: 6/28/2013
- Consent: Yes (unselected), No (unselected), **Test (selected)**, Preview (unselected)
- Non-Enrollment Reason: (empty)
- Off Study: (empty)
- Language: English

A red box highlights the 'Consent' section, and a mouse cursor is pointing at the 'Test' radio button.

## Participant Registration

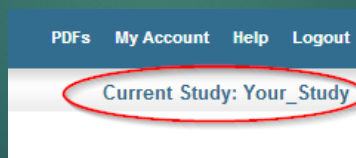
64

- ▶ For some studies, you may want to register participants through the administrative side of the site [for example, if you want to manually select study arms or create specific Logins or Passwords]
- ▶ Otherwise, the Registration process will be included automatically when a participant (or data collector on behalf of a participant) access the administrative side of the site.

## Participant Registration

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- ▶ To begin manual participant registration, go to <https://www.assessmentcenter.net> and login with YOUR login and password.
- ▶ Check to make sure that the study you want to register participants into is the current study by looking at the top right of the screen. If it is not the current study, click the name of your study in the list of studies.



## Participant Registration

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- ▶ The next step is to click on the Administration tab
- ▶ Then click on the "Find/create Login button"

A screenshot of the 'Study Overview' page. At the top, a navigation bar has tabs: Studies, Instruments, Set-up, Preview, and Administration (which is selected and circled in red). Below the tabs, the page title is 'Study Overview' and the study name is 'Study: Your\_Study'. A table shows statistics for the study. Below the table, there is a section for creating or finding participant login records, with a 'Find/create Login' button circled in red.

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	1	1	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

**Find/create Login**

## Participant Registration

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The screenshot shows a 'Participant Registration' form. Red boxes highlight the following sections:

- Study Arm and Schedule:** Includes dropdowns for 'Study Arm' (set to 'Child') and 'Schedule' (set to 'Default'), with a 'View Schedule Details' link.
- Login and Password:** Includes a 'Login: (optional)' field, a 'Password' field with a strength indicator (\*\*), and a checkbox for 'Create participant login'.
- Consent:** Includes radio buttons for 'Consent' with options: Yes, No, Test, and Preview.

Other visible fields include 'Date Approach' (7/3/2013), 'Site' (Internet), 'Study code', 'Baseline', 'Non-Enrollment Reason', 'Off Study', and 'Language' (English). A 'Register Participant' button is at the bottom.

- ▶ On the registration screen you will:
- ▶ Select the Study Arm and Schedule
  - ▶ Create Login – Assessment Center will randomly generate this. If you want to make your own, click the box next to “Create Participant Login”. Creating the login may be helpful for multi-site studies to allow for easier tracking.
  - ▶ Choose a password
  - ▶ Indicate if the participant has consented.
- ▶ If your study collects demographics, contact information, or other information, DO NOT click on “Register Participant, yet.

## Participant Registration

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The screenshot shows the top navigation bar of the system. It includes tabs for 'Studies', 'Instruments', 'Set-up', 'Preview', and 'Administration'. Below these, a sub-navigation bar shows 'Overview', 'Registration Details' (highlighted with a red arrow), 'Participant Details', 'Contact Information', and 'Custom Fields'.

- ▶ To continue entering registration information about the participant, click on the sub sections at the top of the page.
- ▶ Remember that some of the fields can be considered Protected Health Information(PHI) under HIPAA. DO NOT enter this information unless your IRB has approved it being stored on Assessment Center.
  - ▶ PHI includes: name, date of birth, geographic location smaller than state, email address, and others.
- ▶ After you have completed entering registration information, return to the “Registration Details” subsection and click on “Register Participant”.

Register Participant



## Participant Registration

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- ▶ At the bottom of the "Registration Details" page is the custom URL for that participant.
- ▶ Navigating to this URL takes the participant directly into the assessment. No login / password required as it is already part of the URL.
- ▶ If the participant is completing the assessment later or from another computer, he/she would use the study URL and his/her login/password.

The screenshot shows a registration form with the following fields and values:

- Study Arm: Child
- Schedule: Default
- Date Approach: 7/3/2013
- Site: Internet
- Login (optional): P0001
- Password: ABC
- Study code: 6002
- Baseline:
- Consent: Yes (selected)
- Non-Enrollment Reason:
- Off Study:
- Language: English

A red box highlights the URL for the registered participant:

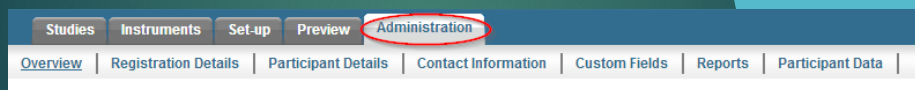
The registered participant can access their study at:  
[https://www.assessmentcenter.net/act/Action.aspx?Module=48&enID=P0001&enPWD=ABC&Action=autologin&Study=Your\\_Study&locale=en-US](https://www.assessmentcenter.net/act/Action.aspx?Module=48&enID=P0001&enPWD=ABC&Action=autologin&Study=Your_Study&locale=en-US)

Register Participant

## Administrative Assessments

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- ▶ If your study has assessments that are completed by the study team, such as medical record abstraction, recording of test scores, etc., return to <https://www.assessmentcenter.net> and log in



- ▶ Go to the Administration tab

## Administrative Assessments

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- ▶ After clicking on the Administration tab, you should be in the "Overview" subsection. Here you will click on "Participant List"

**Study Overview**

Study: Your\_Study

Goal	Participants	Accessed	Study	Registered	Started	Completed	Off Study	Refusal
25	0	2	1	0	0	0	0	0

To create a new participant registration record, click the Find/Create Login button.

Enter participant login then click Find/Create Login button to view an existing participant registration.

[NIH Inclusion Enrollment Report](#)  
[Data Dictionary Report](#)  
[Enrollment Report](#)

To view a list of participants in this study, click the Participant List button below.

## Administrative Assessments

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- ▶ Click on the participant. \*If you have filled in a name, it will be displayed in place of the "ZZZ..."

**Study Participants - Web Access**

Participant	Login	Password	Stcode	Site
zzz-(Missing)	zzz-(Missing)	P0001	ABC	6002 Internet

Studies Instruments Set-up Preview Administration

Overview | Registration Details | Participant Details | Contact Information | Custom Fields | Reports | **Participant Data**

- ▶ Click on the "Participant Data" subsection of the Administration tab



## Administrative Assessments

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- ▶ This screen displays the Assessments for the participant and the responses.
- ▶ Names of completed instruments will be ~~crossed-out~~.
- ▶ To select an instrument, click its name

Login: P0001

Scheduled Events

**Assessment (1)**

1Form(s)

PROMIS Bank v1.0 - Anger

Happiness Rating Scale

PROMIS Bank v1.0 - Applied Cog General Concerns

**Assessment (2)**

**In the past 7 days**

**When I was frustrated, I let it show**

☐ 1 - Never

☐ 2 - Rarely

☐ 3 - Sometimes

☐ 4 - Often

☐ 5 - Always

**In the past 7 days**

**I was irritated more than people knew**

☐ 1 - Never

☐ 2 - Rarely

☐ 3 - Sometimes

☐ 4 - Often

☐ 5 - Always

Save

## Administrative Assessments

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- ▶ As you enter the data into these Administrative assessments, you should click on Save often.

Save

**FREQUENTLY!**

- ▶ If your Assessment Center session times out, unsaved data will be lost.

## APPENDIX H

**Prosthetic model, but not stiffness or height, affects the metabolic cost of running  
for athletes with unilateral transtibial amputations**

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**Abbreviated Title for Running Header**

Prosthetic model affects running biomechanics and economy

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## Abstract

Running-specific prostheses enable athletes with lower limb amputations to run by emulating the spring-like function of biological legs. Current prosthetic stiffness and height recommendations aim to mitigate kinematic asymmetries for athletes with unilateral transtibial amputations. However, it's unclear how different prosthetic configurations influence the biomechanics and metabolic costs of running. Consequently, we investigated how prosthetic model, stiffness, and height affect the biomechanics and metabolic costs of running. Ten athletes with unilateral transtibial amputations each performed fifteen running trials at 2.5 or 3.0 m/s while we measured ground reaction forces and metabolic rates. Athletes ran using three different prosthetic models with five different stiffness category and height combinations per model. Use of an Ottobock 1E90 Sprinter prosthesis reduced metabolic cost by 4.3% and 3.4% compared to use of Freedom Innovations Catapult (fixed effect ( $\beta$ )=-0.177;  $p<0.001$ ) and Össur Flex-Run ( $\beta$ =-0.139;  $p=0.002$ ) prostheses, respectively. Neither prosthetic stiffness ( $p\geq 0.180$ ) nor height ( $p=0.062$ ) affected the metabolic cost of running. The metabolic cost of running was related to lower peak ( $\beta=0.649$ ;  $p=0.001$ ) and stance average ( $\beta=0.772$ ;  $p=0.018$ ) vertical ground reaction forces, prolonged ground contact times ( $\beta=-4.349$ ;  $p=0.012$ ), and decreased leg stiffness ( $\beta=0.071$ ;  $p<0.001$ ) averaged from both legs. Metabolic cost was reduced with more symmetric peak vertical ground reaction forces ( $\beta=0.007$ ;  $p=0.003$ ), but was unrelated to symmetric stride kinematics ( $p\geq 0.636$ ). Therefore, prosthetic recommendations based on stride kinematics do not necessarily minimize the metabolic cost of running. Instead, an optimal prosthetic model, which improves overall biomechanics, minimizes the metabolic cost of running for athletes with unilateral transtibial amputations.

## **New and Noteworthy**

The metabolic cost of running for athletes with unilateral transtibial amputations depends on prosthetic model, and is associated with lower peak and stance average vertical ground reaction forces, longer contact times, and reduced leg stiffness. Metabolic cost is unrelated to prosthetic stiffness, height, and stride kinematic symmetry. Unlike non-amputees who decrease leg stiffness with increased in-series surface stiffness, biological limb stiffness for athletes with unilateral transtibial amputations is positively correlated with increased in-series (prosthetic) stiffness.

**Key Words:** Asymmetry, Prosthesis, Amputee, Economy, Biomechanics

## Introduction

Biological legs behave like linear springs during level-ground running (18, 31, 55). From initial ground contact through mid-stance, tensile forces elongate and store considerable mechanical energy in the elastic structures of the runner's stance leg (i.e. tendons and ligaments) (4, 5, 15, 47, 51, 70). Subsequently, the stored energy is released as the elastic structures recoil and help extend the leg throughout the second half of stance (4). These stance phase running mechanics are well-characterized by a spring-mass model, which depicts the stance leg as a massless linear spring supporting a point mass that represents the runner's center of mass (18, 31, 38, 55) (Fig. 1).

The spring-mass model well-characterizes running mechanics (18, 31, 38, 55, 57), but fails to explain the metabolic cost of running. Unlike the model's depiction, muscles produce force to allow elastic energy storage, thus consuming metabolic energy (49-51). Furthermore, biological legs do not recycle all of the mechanical energy needed to sustain running (15, 47), therefore leg muscles change length while producing force, which may constitute a portion of the metabolic cost of running (63). Moreover, athletes modulate their muscular demands by changing running mechanics, accordingly affecting their metabolic cost. For instance, prolonging ground contact time and reducing stance average ground reaction force (GRF) magnitude during running yields more economical muscular force production (9, 26, 49, 50, 64). Muscular force magnitude also depends on the leg's effective mechanical advantage (16, 17, 48), which along with the rate of producing force (ground contact time), is associated with leg stiffness and step frequency (32, 48) at a given running speed. Thus, by changing stride kinematics and kinetics, athletes may be able to minimize their metabolic cost of running, and improve their distance running performance (28, 45).

The use of passive-elastic running-specific prostheses (RSPs), which emulate the spring-like function of biological legs, allow athletes with unilateral transtibial amputations to run. An RSP connects in-series to the residual limb via a prosthetic socket. RSPs emulate the mechanics of biological legs by storing and returning elastic energy during running (13, 15, 18, 21, 31, 47, 70). Since the commercialization of RSPs in the 1980s (58), the athletic achievements of athletes with transtibial amputations have improved remarkably (43). Ensuing prosthetic design iterations, such as the removal of the prosthetic “heel” component, have further enhanced running performance (43, 46). Yet, despite the improved performance of athletes with transtibial amputations, the prescription of prosthetic model, stiffness, and height are subjective, and may not optimize running performance.

After prosthetists and athletes arbitrarily select a prosthetic model, which vary in design (1-3, 13), prosthetists recommend stiffness and height based on the manufacturer’s recommendations and their own experience. Prosthetic stiffness recommendations are based on the mass of the athlete, with larger/heavier athletes prescribed stiffer RSPs (1-3, 13). The recommended prosthetic stiffness (kN/m) for a given user body mass has yet to be standardized across prosthetic models (13), thus considerable variability exists among recommended prosthetic stiffness. Prosthetic height is recommended so that the affected leg length, which includes the RSP, is 2 to 5 cm longer than the unaffected leg length. In reality, affected leg length is set at the discretion of the prosthetist and athlete, and has been reported to range 0.3 to 8.0 cm taller than the unaffected leg (36, 60). Rather than using subjective prosthetic model, stiffness, and height recommendations that may not optimize the metabolic cost of running (13), we aim to determine whether prosthetic model, stiffness, and/or height affect the metabolic cost

of running, and if so, we seek to determine the prosthetic configuration that minimizes metabolic cost, thus optimizing distance running performance (28, 45).

Previous research of non-amputees indicates that reducing surface stiffness lowers the metabolic cost of running (48, 68), therefore reducing prosthetic stiffness may lower the metabolic cost of running for athletes with unilateral transtibial amputations. While running, non-amputees adjust their leg stiffness to accommodate different surface stiffness so that the combination of their leg and the surface maintains a constant total stiffness (33, 34, 48). They adapt to compliant surfaces in part by better aligning their leg joints with the resultant GRF vector (56), thereby improving the effective mechanical advantage of their leg joints (16, 17, 48). Additionally, compliant elastic surfaces recycle mechanical energy, theoretically mitigating the required muscular work needed to sustain running velocity (48). Together, these biomechanical adaptations to running on compliant surfaces have been related to a reduced metabolic cost of running (48, 68). For example, Kerdok et al. (48) reported that a 12.5 fold decrease in surface stiffness reduced the metabolic cost of running 3.7 m/s by 12% (48). Hence, reduced prosthetic stiffness compared to the manufacturer recommended stiffness may lower the metabolic cost of running for athletes with unilateral transtibial amputations due to decreased muscular work and improved residual limb stiffness (better effective mechanical advantage).

Prosthetic height may also influence the metabolic cost of running. Increased prosthetic height may prolong the affected leg's ground contact time (73, 74), enabling more economical force production (49, 62). Alternatively, the effective mechanical advantage of the leg joints would worsen with invariant joint angles and taller prostheses. Nonetheless, it is unknown whether prosthetic height affects the metabolic cost of running for athletes with unilateral transtibial amputations.



Athletes with unilateral transtibial amputations exhibit asymmetric stride kinematics and kinetics (10, 12, 22, 27, 36, 41, 42, 54, 61, 66, 75), which are likely a consequence of the RSPs' inability to replicate biological lower leg function. Accordingly, prosthetic manufacturers and prosthetists recommend stiffness and height configurations that mitigate stride kinematic asymmetries between the legs of athletes with unilateral transtibial amputations (1-3). In line with these recommendations, a preliminary study by Wilson et al. (75) reported that changing prosthetic stiffness and height altered the stride kinematic and kinetic asymmetry for two athletes with unilateral transtibial amputations during running. Perhaps the metabolic cost of running is correlated with the severity of stride kinematic and/or kinetic asymmetry. Previous studies have reported positive associations between stride kinematic and kinetics asymmetries and the metabolic cost of walking for young healthy subjects (29, 35), and for individuals with unilateral transtibial amputations (39). On the other hand, Mattes et al. (53) reported that the metabolic cost of using passive prostheses during walking for individuals with unilateral transtibial amputations is greater when lower limb mass and moments of inertia are symmetric between legs. Yet, it is uncertain if these walking studies translate to running. Seminati et al. (67) reported that non-amputees with slightly asymmetric lower limbs run with more pronounced stride kinematic asymmetries while consuming metabolic energy at the same rate as non-amputees with symmetric lower limbs and biomechanics. Additionally, Brown et al. (20) reported that athletes with unilateral transtibial amputations (with presumably asymmetric biomechanics) consume oxygen at similar rates as age and fitness matched non-amputees (with presumably symmetric biomechanics) across running speeds; indicating that asymmetric running biomechanics may not exacerbate the metabolic cost of running for athletes with unilateral transtibial amputations. Due to the current prescription of RSPs, which aim to minimize kinematic asymmetries for athletes

with unilateral transtibial amputations, we seek to investigate how different prosthetic configurations affect the stride kinematic and kinetic asymmetries of athletes with unilateral transtibial amputations, and whether these asymmetries are associated with the metabolic cost of running.

The purpose of our study was to determine the prosthetic model, stiffness, and height configuration that minimizes the metabolic cost of running for athletes with unilateral transtibial amputations, thus optimizing distance running performance (28, 45). To explain the potential effects of prosthetic configuration on metabolic cost, we also determined the associations between prosthetic model, stiffness, and height on the elicited biomechanics (overall and asymmetric). We also investigated the relationships between running biomechanics (overall and asymmetric) and metabolic cost. We hypothesized that the metabolic cost of running for athletes with unilateral transtibial amputations would be minimized when they used an RSP less stiff than the respective manufacturer's recommended stiffness category and when they used an RSP set at the manufacturer/prosthetist recommended height. We hypothesized that leg stiffness would be invariant across different prosthetic stiffness, thus residual limb stiffness would be inversely correlated with prosthetic stiffness. We also hypothesized that the metabolic cost of running for athletes with unilateral transtibial amputations would be correlated with overall and asymmetric biomechanics. Lastly, we hypothesized that the prosthetic model, stiffness, and height that minimize metabolic cost would be associated with the biomechanical variables that optimize the metabolic cost of running. Due to their influence on the metabolic cost of running, we investigated the following biomechanical variables: peak and stance average vertical GRFs (49, 50, 71), peak horizontal GRFs (9, 26), ground contact time (49, 50), stride frequency (25, 44, 69), and leg stiffness (25, 32, 44, 69).

## METHODS

### *Subjects*

Ten athletes with a unilateral transtibial amputation (seven males and three females) participated (Table 1). Each participant had at least one year of experience running using a passive-elastic RSP and gave informed consent according to our protocol, which was approved by the Colorado Multiple Institutional Review Board and the USAMRMC Office of Research Protection, Human Research Protection Office.

### *Protocol*

Initially, each participant completed an alignment and accommodation session, which entailed a certified prosthetist aligning each participant with three different prosthetic models (Freedom Innovations Catapult FX6, Irvine, CA, USA; Össur Flex-Run, Reykjavik, Iceland; Ottobock 1E90 Sprinter, Duderstadt, Germany) at each manufacturer's recommended stiffness category and  $\pm 1$  stiffness category, and at each manufacturer's recommended prosthetic height and  $\pm 2$  cm. The Catapult and Flex-Run prostheses are "C" shaped and attach distally to the socket via a connective aluminum pylon (Fig. 2). The 1E90 Sprinter prosthesis is "J" shaped and mounts to the posterior wall of the socket. After establishing the height for a J-shaped prosthesis, the device is typically bolted directly to the socket. For this study, we constructed a custom aluminum height adjustment bracket that was bolted to an athlete's socket, allowing us to secure the 1E90 Sprinter prosthesis to the socket, alter prosthetic height between trials, while preserving the RSP (Fig. 2).

During the accommodation session, participants ran using each prosthetic model on a treadmill at self-selected speeds until both the participant and prosthetist were satisfied with the

recommended height and the alignment at each height. Generally, athletes accommodated to each prosthetic model at the recommended stiffness category and height. For the C-shaped RSPs, the athletes ran at all three heights (recommended and  $\pm 2$  cm) to determine proper alignment for each connective pylon. For the J-shaped RSP, the alignment of the custom bracket that connected the RSP to the socket remained unaltered across height conditions, thus athletes did not typically accommodate to the non-recommended heights prior to the experimental sessions.

On subsequent days, participants performed a five minute standing trial (using their personal walking prosthesis) and up to six, five minute running trials per session with at least five minutes of rest between trials. Participants ran on a 3D force-measuring treadmill (Treadmetrix, Park City, UT, USA) at 3 m/s. If a participant was unable to maintain primarily oxidative metabolism at 3 m/s, indicated by a respiratory exchange ratio  $> 1.0$ , running speed was reduced to 2.5 m/s. All running trials for a participant were performed at the same speed; therefore, if running speed was reduced to 2.5 m/s, all of the trials for the respective participant were (re)tested at 2.5 m/s.

Each participant ran using 15 different combinations of prosthetic model, stiffness category, and height. Initially, participants ran using each prosthetic model at three different stiffness categories (recommended and  $\pm 1$ ) and the recommended affected leg length (nine trials, three per prosthetic model). The stiffness category for each prosthetic model that elicited the lowest net metabolic cost of transport (CoT in J/kg/m) was deemed optimal. Subsequently, participants ran using the optimal stiffness category of each prosthetic model at two additional affected leg lengths ( $\pm 2$  cm) (six additional trials). We randomized the trial order beginning with the nine prosthetic model and stiffness category combinations at the recommended affected leg length. Once a participant completed trials at all three stiffness categories for a prosthetic model

at the recommended affected leg length, the height alteration trials for the respective prosthetic model at the optimal stiffness category were randomly inserted into the trial order. We tested each participant at the same time of day for all of their sessions to minimize any potential day-to-day variability.

### *Prosthetic Stiffness*

The recommended prosthetic stiffness (kN/m) for each prosthetic model varies (13). Accordingly, we evaluated the influence of each manufacturer's recommended prosthetic stiffness category, as well as the influence of actual prosthetic stiffness (kN/m) on the net CoT during running using recently published data from our lab (13). Concisely, we calculated prosthetic stiffness using the mean peak vertical GRF magnitude measured from the affected leg during each trial (present study) and estimated prosthetic displacement using the force-displacement equations from Beck et al. (13). Subsequently, we divided the measured peak GRF magnitude by the respective RSP displacements to yield prosthetic stiffness.

### *Biomechanics*

Participants ran on a 3D force-measuring treadmill. We collected and analyzed the vertical and anterior-posterior components of the ground reaction forces (GRFs) during the last two minutes of each trial. We collected GRFs at 1000 Hz and filtered them using a 4<sup>th</sup> order low pass Butterworth filter with a 30 Hz cutoff. We used the filtered data to calculate peak and stance average vertical GRFs, peak horizontal (braking and propulsive) GRFs, in addition to ground contact time, step frequency, and leg stiffness values from 10 consecutive strides (10 affected leg steps and 10 unaffected leg steps) with a custom MATLAB script (Mathworks Inc., Natick, MA,

USA). To detect periods of ground contact, we set the vertical GRF threshold to 1% of participant bodyweight.

Leg stiffness ( $k_{leg}$ ) was computed as the quotient of peak vertical GRF ( $F_{peak}$ ) and the maximum compression of the leg spring ( $\Delta L$ ) during ground contact (Fig. 1), as per Farley et al. (31).

$$k_{leg} = \frac{F_{peak}}{\Delta L} \quad [1]$$

To calculate the maximum compression of the leg spring ( $\Delta L$ ), we measured initial unaffected leg length ( $L_0$ ) from the greater trochanter to the floor during standing, and affected leg length ( $L_0$ ) as the distance from the greater trochanter to the distal end of the unloaded RSP (14, 36, 54). Next, we used initial leg lengths to calculate theta ( $\theta$ ), which is the angle of the leg spring at initial ground contact relative to vertical.

$$\theta = \sin^{-1}\left(\frac{v t_c}{2 L_0}\right) \quad [2]$$

Mathematically, theta ( $\theta$ ) equals half the angle swept by the stance leg, as determined from running velocity ( $v$ ), ground contact time ( $t_c$ ), and initial leg length ( $L_0$ ). The maximum stance leg spring compression ( $\Delta L$ ) was calculated using equation 3,

$$\Delta L = \Delta y + L_0(1 - \cos \theta) \quad [3]$$

which incorporates the peak vertical displacement of the center of mass during ground contact ( $\Delta y$ ), calculated by twice integrating the vertical acceleration of the center of mass with respect to time (23). The instantaneous vertical acceleration of the center of mass was calculated by

subtracting the participant's bodyweight from the vertical GRF magnitude (net force), and dividing by body mass (23).

Since biological legs and RSPs act as relatively linear springs (13, 30, 31, 37), we modeled the affected leg stiffness as two in-series linear springs comprised of the RSP and residual limb (Fig. 1; Equation 4).

$$\frac{1}{k_{leg}} = \frac{1}{k_{RSP}} + \frac{1}{k_{res}} \quad [4]$$

Thus, we used the measured leg stiffness ( $k_{leg}$ ) and the calculated prosthetic stiffness ( $k_{RSP}$ ) to solve for the residual limb stiffness ( $k_{res}$ ) during running.

To assess inter-limb symmetry, we used the absolute value of the symmetry index (40, 65, 75) expressed as a percentage (Equation 5). Taking the absolute value of the symmetry index is necessary to discern symmetry from asymmetry using linear statistical models. Perfect inter-limb symmetry is equal to zero percent.

$$\left| \frac{UL - AL}{0.5 (UL + AL)} \right| \times 100 \quad [5]$$

Due to the potential association between RSP mechanical energy return and the metabolic cost of running, we calculated absolute mechanical energy return per affected leg step ( $\dot{E}_{step}$ ),

$$\dot{E}_{step} = \frac{1}{2} k_{RSP} (\Delta d)^2 (1 - Hyst_{RSP}/100) \quad [6]$$

determined from prosthetic stiffness ( $k_{RSP}$ ), peak prosthetic displacement ( $\Delta d$ ), and percent prosthetic hysteresis ( $Hyst_{RSP}$ ) (13). Next, we divided absolute mechanical energy return ( $\dot{E}_{RSP}$ )

by user body mass ( $m$ ) and stride length ( $L_{stride}$ ) to calculate normalized mechanical energy return ( $\dot{E}_{RSP}$ ) per stride (J/kg/m).

$$\dot{E}_{RSP} = \frac{\dot{E}_{step}}{m (L_{stride})} \quad [7]$$

### *Metabolic Cost of Transport*

We instructed participants to fast for at least three hours prior to testing. We measured each participant's rate of oxygen consumption ( $\dot{V}O_2$ ) and carbon dioxide production ( $\dot{V}CO_2$ ) using open-circuit expired gas analysis (TrueOne 2400, ParvoMedic, Sandy, UT, USA) throughout each trial and averaged these rates during the last two minutes of each trial to calculate steady-state metabolic power (W) using a standard equation (19). Then, we subtracted the average metabolic power consumed during standing of the corresponding day from each running trial to yield net metabolic power. We normalized net metabolic power by the mass of each participant, which included running gear (e.g. RSP, socket, shoe, and clothes) for each respective trial. Finally, to combine data from 3.0 and 2.5 m/s, we divided net metabolic power by running velocity to calculate the net metabolic cost of transport (CoT) in J/kg/m.

### *Statistical Analyses*

We used a linear mixed model to evaluate the effects of using different prosthetic models, stiffness categories, and heights on net CoT. We used a second linear mixed model to evaluate the effects of using different prosthetic models, actual prosthetic stiffness (kN/m), and heights on net CoT. We used linear regressions to assess the independent relationships between affected leg stiffness, prosthetic stiffness, and residual limb stiffness. We also tested whether affected and unaffected leg stiffness are correlated, and if net CoT is influenced by the absolute RSP



mechanical energy return per step (Equation 7) and/or per unit distance traveled (Equation 5) with linear regressions.

Four participants ran at 3.0 m/s and six ran at 2.5 m/s. For this reason we used additional linear mixed models to control for speed while independently testing the associations between overall (affected leg and unaffected leg averaged) and asymmetric GRFs (stance average vertical GRF, peak vertical GRF, and peak horizontal braking and propulsive GRFs), stride kinematics (ground contact time and step frequency), and leg stiffness on net CoT. We also performed a linear mixed model to evaluate the relationship between prosthetic model, stiffness, and height on the overall and asymmetric biomechanical variables that influence net CoT.

We used paired two-tailed t-tests to assess leg length discrepancies between affected and unaffected legs and implemented Bonferroni corrections when appropriate. For the linear mixed models and linear regressions, we report the fixed effect ( $\beta$ ) from each statistically significant association (dependent variable =  $\beta$  independent variable + intercept). We tested all potential independent variable interactions with linear mixed models. If independent variables or interactions were non-significant, they were dropped from the model for the interpretation of the significant variables and interactions. We set the level of significance at  $\alpha=0.05$ , and performed all statistical analyses using R-studio software (Boston, MA, USA).

## RESULTS

All prosthetic models were set at statistically similar recommended heights ( $p \geq 0.053$ ) (Table 1). The recommended affected leg lengths were statistically longer than the corresponding unaffected leg lengths when using the Catapult ( $1.01 \pm 0.07$  m;  $p < 0.001$ ) and Flex-Run prostheses ( $1.00 \pm 0.07$  m;  $p = 0.001$ ), but not when using the 1E90 Sprinter prosthesis ( $0.98 \pm$

0.07 m; Bonferroni corrected  $p=0.080$ ). Furthermore, our highest stiffness category Flex-Run prosthesis was the manufacturer recommended stiffness category for two participants. Hence, these participants were tested at the stiffness categories of recommended, -1, and -2 with the Flex-Run prosthesis. Due to residual leg lengths and component heights, we were unable to perfectly match prosthetic heights at -2 cm for five participants. Therefore, the actual prosthetic heights for the shortest condition for five participants were -1.2, -1.3, -2.6, -0.5, and -1.2 cm with the C-shaped RSPs. We accounted for these disparities with our statistical analyses. Additionally, due to RSP component and logistical limitations, we were unable to complete four trials for three different participants; hence our results include 146 trials (Table 2) rather than 150 (15 trials per 10 participants).

While controlling for covariates (i.e. controlling for two of the following while assessing the third: prosthetic model, stiffness, and height), the net CoT for athletes with unilateral transtibial amputations was independent of prosthetic stiffness category ( $p=0.180$ ), actual prosthetic stiffness ( $p=0.327$ ) (Fig. 3), and height ( $p=0.062$ ). In contrast, prosthetic model had a significant effect on net CoT. Use of a 1E90 Sprinter prosthesis resulted in 4.3% and 3.4% lower net CoT compared to use of the Catapult ( $\beta=-0.177$ ;  $p<0.001$ ) and Flex-Run ( $\beta=-0.139$ ;  $p=0.002$ ) prostheses, respectively. Net CoT was similar with use of the Catapult versus Flex-Run prosthesis ( $p=0.393$ ) (Fig. 3). There were no prosthetic model, stiffness, or height interactions affecting net CoT ( $p\geq 0.151$ ).

The affected leg stiffness of athletes with unilateral transtibial amputations was positively correlated with prosthetic stiffness ( $p<0.001$ ;  $R^2=0.708$ ; affected leg stiffness =  $0.558$  prosthetic stiffness +  $0.814$ ) (Fig. 4) and residual limb stiffness ( $p<0.001$ ;  $R^2=0.728$ ; affected leg stiffness =  $0.196$  residual limb stiffness +  $6.777$ ). Increased prosthetic stiffness was associated with

increased residual limb stiffness ( $p < 0.001$ ;  $R^2 = 0.212$ ; Residual limb stiffness =  $0.159$  prosthetic stiffness +  $17.336$ ) (Fig. 4). Unaffected leg stiffness was positively correlated with affected leg stiffness ( $p < 0.001$ ;  $R^2 = 0.509$ ; unaffected leg stiffness =  $0.693$  affected leg stiffness +  $5.270$ ), and prosthetic stiffness ( $p < 0.001$ ;  $R^2 = 0.398$ ; unaffected leg stiffness =  $0.398$  prosthetic stiffness +  $5.583$ ).

The majority of overall (affected leg and unaffected leg average) biomechanical parameters affected net CoT. Namely, for every  $0.1$  times bodyweight reduction in peak ( $\beta = 0.649$ ;  $p = 0.001$ ) and stance average vertical GRF ( $\beta = 0.772$ ;  $p = 0.018$ ), net CoT decreased  $2.6\%$ . For every  $0.1$  second increase in ground contact time, net CoT decreased  $8.4\%$  ( $\beta = -0.435$ ;  $p = 0.012$ ). For every  $1$  kN/m reduction in leg stiffness, net CoT decreased  $2.3\%$  ( $\beta = 0.071$ ;  $p < 0.001$ ). Net CoT was not affected by peak horizontal braking ( $p = 0.502$ ) or propulsive ( $p = 0.899$ ) GRFs, nor step frequency ( $p = 0.773$ ). Additionally, neither the amount of RSP mechanical energy returned per step nor per unit distance traveled influenced net CoT ( $p \geq 0.060$ ).

Of the investigated stride kinematic and kinetic asymmetries, net CoT was only related to peak vertical GRF asymmetry ( $\beta = 0.007$ ;  $p = 0.003$ ) (Fig. 5). Across all prosthetic configurations, for every  $10.0\%$  reduction in peak vertical GRF asymmetry, net CoT decreased  $1.9\%$ . For perspective, if the mean elicited peak vertical GRF asymmetry ( $15.7\%$ ) between the affected and unaffected legs became perfectly symmetric ( $0.0\%$ ), net CoT would decrease  $3.0\%$ . The elicited net CoT was independent of the following asymmetries: stance average vertical GRF ( $p = 0.410$ ), peak braking ( $p = 0.119$ ) and peak propulsive ( $p = 0.917$ ) horizontal GRF, ground contact time ( $p = 0.867$ ), step frequency ( $p = 0.754$ ), and leg stiffness ( $p = 0.636$ ) (Table 3 and Table 4). Within our protocol, running speed did not alter the influence of biomechanics on metabolic cost ( $p \geq 0.170$ ).

Increased prosthetic stiffness (kN/m) resulted in greater stance average vertical GRFs ( $\beta=0.007$ ;  $p<0.001$ ), shorter ground contact times ( $\beta=-0.002$ ;  $p<0.001$ ) (Table 3 & Fig. 6), and greater leg stiffness ( $\beta=0.194$ ;  $p<0.001$ ) (Table 3). Increased prosthetic height resulted in more asymmetric peak vertical GRFs ( $\beta=4.062$ ;  $p<0.001$ ) (Table 4 and Fig. 7). The 1E90 Sprinter prosthesis resulted in greater stance average vertical GRF compared to the Catapult ( $\beta=0.033$ ;  $p=0.001$ ) but not Flex-Run prosthesis ( $p=0.137$ ), longer ground contact time ( $\beta=0.008$ ;  $p<0.001$ ) compared to the Flex-Run but not the Catapult ( $p=0.395$ ) prosthesis, and lower leg stiffness compared to both C-shaped RSPs ( $\beta\geq-0.556$ ;  $p<0.001$ ). The 1E90 Sprinter prosthesis resulted in 8.3 to 8.7% (symmetry index percentage) more symmetric peak vertical GRFs compared to the use of the C-shaped RSPs ( $p<0.001$ ) (Fig. 6 and Fig. 7). Neither prosthetic model, stiffness, nor height affected overall peak vertical GRF magnitude ( $p\geq0.050$ ). Prosthetic stiffness was independent of peak vertical GRF asymmetry ( $p=0.108$ ) (Table 3 and Fig. 6), and prosthetic height was independent of stance average vertical GRF ( $p=0.959$ ), ground contact time ( $p=0.353$ ), and leg stiffness ( $p=0.348$ ).

## DISCUSSION

Within the study's parameters, neither prosthetic stiffness nor height affected the net CoT during running for athletes with unilateral transtibial amputations; therefore, we reject our initial hypothesis. Unlike prosthetic stiffness and height, net CoT was affected by prosthetic model. The use of the J-shaped 1E90 Sprinter prosthesis lowered the metabolic cost of running compared to the use of the C-shaped Catapult and Flex-Run prostheses; the 1E90 Sprinter prosthesis was metabolically optimal for 9 out of 10 athletes. These results occurred despite the heavier custom

385 bracket used for the 1E90 Sprinter prosthesis compared to the typical J-shaped RSP  
386 configuration. Rather than bolting the prosthesis directly to the socket, we used a relatively large  
387 bracket (~400 g) to connect the RSP to the socket (Fig. 2). As a result, the combined mass of the  
388 1E90 Sprinter prosthesis and attachment was ~425 g greater than that of the Catapult and Flex-  
389 Run prostheses. Previous non-amputee running studies demonstrate that adding 100 g to each  
390 foot increases the metabolic cost of running by ~1% (24, 45, 52), indicating that our testing  
391 configuration for the 1E90 Sprinter prosthesis may have artificially increased the metabolic cost  
392 of running. Thus, the lower metabolic cost while using the J-shaped 1E90 Sprinter prosthesis  
393 versus the use of C-shaped prostheses would have likely been further reduced through the use of  
394 a typical, light weight, configuration.

395         The best prosthetic configuration (model, stiffness, and height combination) for each  
396 participant resulted in an 18.9% lower net CoT compared to the worst configuration (paired t-  
397 test;  $p < 0.001$ ;  $3.65 \pm 0.37$  vs.  $4.50 \pm 0.45$  J/kg/m). Our results coincide with previous research  
398 demonstrating the sensitivity of the metabolic cost of running to prosthetic model for athletes  
399 with unilateral transtibial amputations (46, 72). In 1999, Hsu et al. (46) reported that athletes  
400 with unilateral transtibial amputations consumed oxygen at 8 – 11% greater rates while running  
401 at 2.01 – 2.45 m/s using a solid-ankle cushioned heel (SACH) prosthesis compared to using a  
402 passive-elastic Re-Flex Vertical Shock Pylon prosthesis. The SACH prosthesis uses a static, rigid  
403 design whereas the Re-Flex Vertical Shock Pylon prosthesis uses a vertical leaf spring and  
404 piston-cylinder pylon design (46). In 2009, Brown et al. (20) reported that athletes with  
405 transtibial amputations consumed 14% less oxygen while running at 2.23 m/s using RSPs (the  
406 athlete's personal RSP), similar to those used in the present study, compared to using relatively  
407 rigid passive-elastic walking prostheses that have an incorporated "heel" component.

Remarkably, the most and least economical RSPs for each participant in the present study elicited a wider range of metabolic costs compared to the previous research that compared the use of RSPs to walking prostheses (20, 46). This may be due to inconsistent sagittal plane alignment, the use of different sockets, and/or the faster running speeds used in the present study compared to previous investigations (20, 46). Altogether, prosthetic model strongly influences the metabolic cost of running for athletes with unilateral transtibial amputations.

We reject our second hypothesis because residual limb stiffness was positively correlated with prosthetic stiffness (Fig. 4). This positive correlation accentuated the leg stiffness changes of our participants with altered in-series (prosthetic) stiffness, contrasting that of non-amputee runners (33, 34, 48). Consequently, running mechanics and center of mass dynamics of athletes with unilateral transtibial amputations may be affected by the in-series (RSP or surface) stiffness (Table 3 and Fig. 6). The residual limb stiffness of athletes with bilateral transtibial amputations are also positively correlated with prosthetic stiffness (14), indicating that the absence of biological lower legs may yield novel biomechanical adaptations to in-series stiffness changes.

Due to the effects of different biomechanical parameters on the metabolic cost of running, we accept our third hypothesis. Regarding overall biomechanics, the metabolic cost of running was reduced with lower peak and stance average vertical GRFs, longer ground contact times, and decreased leg stiffness (Table 3 and Table 4). Thus, it is likely that the optimal combination of these biomechanical variables minimize the metabolic cost of running for athletes with unilateral transtibial amputations. For instance, in our study, running with compliant leg springs resulted in prolonged ground contact time and decreased stance average vertical GRFs. Longer ground contact time extends the duration that athletes are able to generate force on the ground, enabling the recruitment of slower, more economical muscle fibers (49, 62).

Lower stance average vertical GRFs reduce the number of active, ATP consuming actin-myosin cross-bridges needed to sustain running (49, 62). However, reduced leg stiffness also decreases the effective mechanical advantage of the leg joints. Thus, there is likely an optimal leg stiffness that elicits the ideal combination of the rate and magnitude of muscular force production. Furthermore, reduced peak vertical GRF asymmetries resulted in an improved metabolic cost of running for athletes with unilateral transtibial amputations. Within the range of observed asymmetries, peak vertical GRF asymmetry was the only such parameter that changed net CoT. Six of the seven observed asymmetries had no effect on the metabolic cost of running, including all of the measured stride kinematics. Therefore, current prosthetic prescriptions, which aim to mitigate stride kinematic asymmetries (1-3), may not necessarily minimize the metabolic cost of running. Rather, prosthetic prescriptions focused on both legs' biomechanics may optimize the distance running performance of athletes with unilateral transtibial amputations.

Our last hypothesis was supported because the J-shaped prosthetic model that minimized the metabolic cost of running for athletes with unilateral transtibial amputations was associated with reduced leg stiffness, and more symmetric peak vertical GRFs compared to the use of the C-shaped RSPs ( $p < 0.001$ ). In addition, the use of the 1E90 Sprinter prosthesis may have led to enhanced sagittal plane alignment, and/or improved lateral balance during running compared to the C-shaped RSPs. The sagittal plane alignment of the 1E90 Sprinter prosthesis may have yielded shorter GRF-leg joint moment arms, mitigating joint moments and the muscular force requirements during running (16, 17). Moreover, through a series of studies Arellano and Kram (6-9) demonstrated that there is a measureable metabolic cost associated with maintaining lateral balance during running. Hence, the wider (0 to 2.5 cm) and thicker (0.1 to 0.9 cm) design of the 1E90 Sprinter prosthesis versus the C-shaped RSPs at each segment (i.e. proximal, medial,



distal) (1-3) may have improved lateral balance, consequently reducing the metabolic cost of running.

It has been widely accepted that athletes with unilateral transtibial amputations generate lower peak and stance average vertical GRFs with their affected leg compared to their unaffected leg (11, 36, 41, 54, 61). Our study supports this notion; the unaffected leg of our participants averaged 15.4% greater peak vertical GRFs than those of the affected leg. Lower affected leg peak vertical GRFs have been attributed to residual limb discomfort (61), weakness (36), as well as to the lack of net positive RSP mechanical power (36, 54). However, our data indicate that peak vertical GRF asymmetry occurred because of unequal leg lengths. The affected leg's peak vertical GRF production is inversely correlated with its relative length (linear regression;  $p < 0.001$ ;  $R^2 = 0.417$ ; peak vertical GRFs =  $-0.052$  relative affected leg length (cm) + 2.449) (Fig. 7). Unaffected leg peak vertical GRFs were independent of affected leg length (linear regression;  $p = 0.052$ ). Of our study's 18 trials (spanning 5 participants) where affected leg length was shorter or equal to unaffected leg length, the peak ( $p = 0.421$ ) and stance average ( $p = 0.686$ ) vertical GRFs were statistically similar between legs. Simply stated, reducing affected leg length, by decreasing prosthetic height, yields more symmetric peak and stance average vertical GRFs between the legs of athletes with unilateral transtibial amputations (Fig. 7).

Future studies are needed to optimize RSP configuration across multiple amputation levels (e.g. transfemoral, transtibial, etc.) and over a broad range of athletic endeavors (e.g. sprinting, cycling, and jumping). Socket design may also influence the metabolic cost of running. In the current study, our participants used two different sockets to complete the protocol (one for C-shaped RSPs and one for the J-shaped RSP). As a result, there may have been unequal residual limb movement within the different sockets, potentially leading to varying levels of muscular



contraction, which may have affected the metabolic cost of running (59). Additionally, the use of two separate testing speeds may have limited our study, however we verified that running speed did not affect net CoT ( $p=0.454$ ) or any of the investigated biomechanical parameters ( $p\geq 0.170$ ) using linear mixed models. We risk reporting type I errors due to our procedure of assessing each dependent variable with a separate statistical test. In addition, the effect of prosthetic height may have been confounded by our pseudo-randomized trial order. Ideally, height alteration trials would have been inserted into the initial randomized trial order rather than after all the prosthetic stiffness category trials at the recommended height for each of the respective prosthetic models.

## CONCLUSIONS

Prosthetic model, but not stiffness or height, affected the metabolic cost of running for athletes with unilateral transtibial amputations. The use of a J-shaped, 1E90 Sprinter prosthesis elicited lower metabolic costs during running compared to the use of C-shaped prostheses. Furthermore, athletes with transtibial amputations appear to modulate biological leg stiffness with altered in-series stiffness differently than non-amputees. As such, changes to in-series prosthetic stiffness and surface stiffness likely alter the running mechanics of athletes with unilateral transtibial amputations. Despite the current prescriptions of running-specific prostheses, which aim to mitigate kinematic asymmetries between the affected and unaffected legs of athletes with unilateral transtibial amputations, the metabolic cost of running was independent of stride kinematic asymmetries, and only related to one kinetic asymmetry (peak vertical GRFs). Instead, the metabolic cost of running was reduced with decreased overall (affected and unaffected leg average) peak and stance average vertical GRFs, prolonged ground

contact times, and reduced leg stiffness. Therefore, current prosthetic manufacturer recommendations do not necessarily reduce the metabolic cost of running (or optimize distance-running performance). Instead, recommendations based on prosthetic design and the affected and unaffected leg's average biomechanics, rather than asymmetries, likely optimize distance-running performance for athletes with unilateral transtibial amputations.

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## Disclosures

The authors have no conflicts of interest to disclose. All of the running-specific prostheses used in our study were donated from the respective manufacturer.

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**Figure 1.** A) Illustration of the spring-mass model of running for non-amputees and the unaffected leg of athletes with a transtibial amputation. B) Illustration of a spring-mass model of running with an in-series leg spring for the affected leg of athletes with a transtibial amputation. Body mass is represented as a point mass (circle) and the touch-down angle is indicated by  $\theta$  ( $\theta$ ). The stance leg is represented by a massless linear spring (A), or two in-series massless linear springs (B). The initial leg length ( $L_0$ ) shortens ( $\Delta L$ ), as its vertical height ( $\Delta y$ ) lowers during the stance phase of running. Modeled residual limb length ( $Res_0$ ) and prosthetic height ( $RSP_0$ ) compress ( $\Delta Res$  and  $\Delta RSP$ ) during the stance phase of running.

**Figure 2.** A) Freedom Innovations Catapult FX6 prosthesis (C-shaped) at a representative recommended height, B) Össur Flex-Run prosthesis (C-shaped) at a representative height of +2 cm, and C) Ottobock 1E90 Sprinter prosthesis (J-shaped) at a representative height of -2 cm. The C-shaped prostheses are connected beneath the socket via an aluminum pylon, and the J-shaped prosthesis is connected behind the socket via a custom aluminum bracket.

**Figure 3.** A) The average ( $\pm$ SE) net cost of transport (CoT) across prosthetic stiffness categories (Cat) for each prosthetic model. B) The average ( $\pm$ SE) net CoT across recommended (Rec) and  $\pm 2$  cm prosthetic height alterations. Triangles represent Catapult prostheses, squares indicate Flex-Run prostheses, and diamonds signify 1E90 Sprinter prostheses. Symbols are offset for visual representation. See table 2 for sample size in visual depiction. We performed linear mixed models from all of our collected data to determine that there was no effect of stiffness category ( $p=0.180$ ) or height ( $p=0.062$ ) on net CoT, and that net CoT was reduced when participants used

the 1E90 Sprinter prosthesis compared to using the Catapult ( $p < 0.001$ ) or Flex-Run ( $p = 0.002$ ) prosthesis.

**Figure 4.** A) Residual limb stiffness compared to running-specific prosthetic (RSP) stiffness ( $p < 0.001$ ), and B) Affected leg stiffness compared to prosthetic stiffness. We performed linear regressions across all collected data to determine significant correlations between A) residual limb stiffness and RSP stiffness ( $p < 0.001$ ), as well as between B) affected leg stiffness and RSP stiffness ( $p < 0.001$ ).

**Figure 5.** Individual net cost of transport (CoT) values plotted as a function of absolute peak vertical ground reaction force (GRF) asymmetry. Triangles represent Catapult prostheses, squares indicate Flex-Run prostheses, and diamonds signify 1E90 Sprinter prostheses. Using all of our collected data, we performed a linear mixed model to determine that reducing peak vertical GRF asymmetry lowered net CoT (net CoT =  $0.007$  peak vertical GRF asymmetry +  $3.933$ ).

**Figure 6.** Mean vertical and horizontal ground reaction forces (GRFs) from ten consecutive affected (dashed line) and unaffected (solid line) leg steps from a representative participant running at  $3$  m/s. Columns left to right indicate the Freedom Innovations Catapult FX6, Össur Flex-Run, and Ottobock 1E90 Sprinter prostheses. Rows top to bottom indicate prosthetic stiffness category:  $-1$ , recommended (Rec), and  $+1$ .

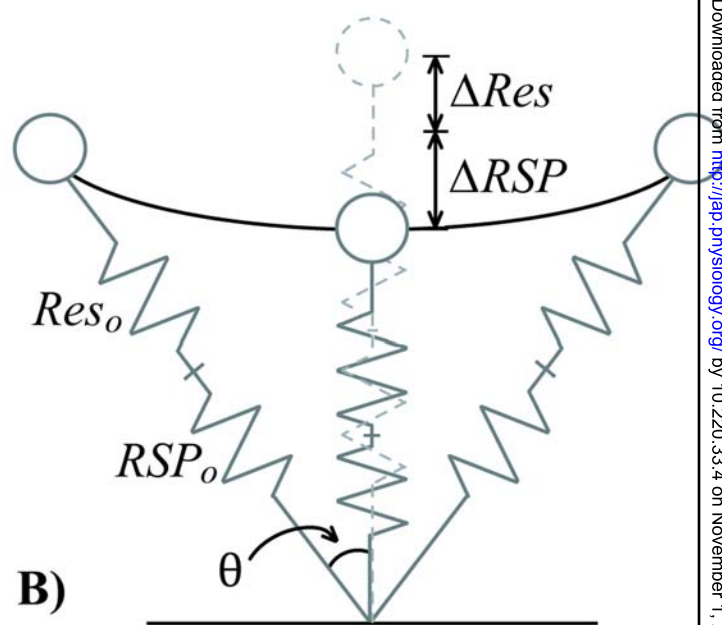
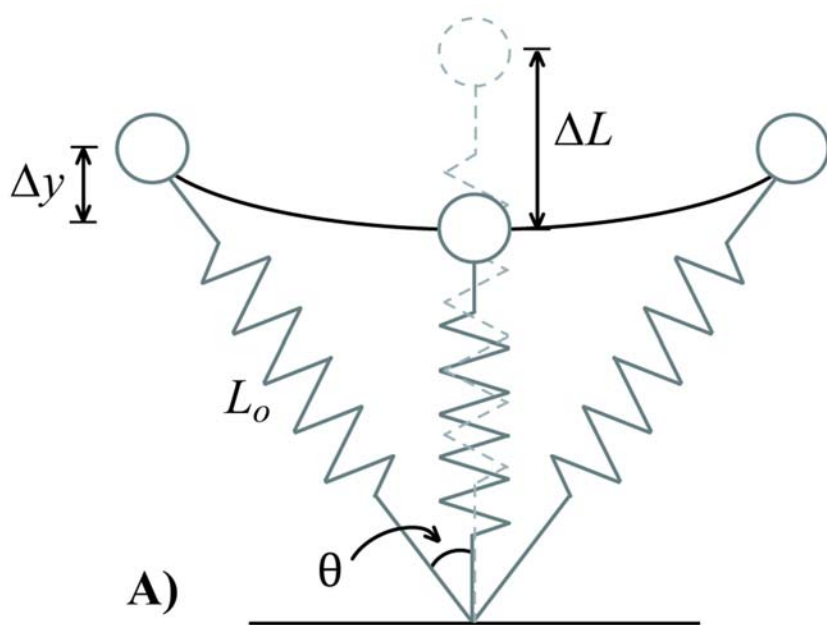
733 **Figure 7.** Mean vertical and horizontal ground reaction forces (GRFs) from ten consecutive  
734 affected (dashed line) and unaffected (solid line) leg steps from a representative participant  
735 running at 3 m/s. Columns left to right indicate the Freedom Innovations Catapult FX6, Össur  
736 Flex-Run, and Ottobock 1E90 Sprinter prostheses. Rows top to bottom indicate prosthetic height:  
737 +2 cm, recommended (Rec), and -2 cm.  
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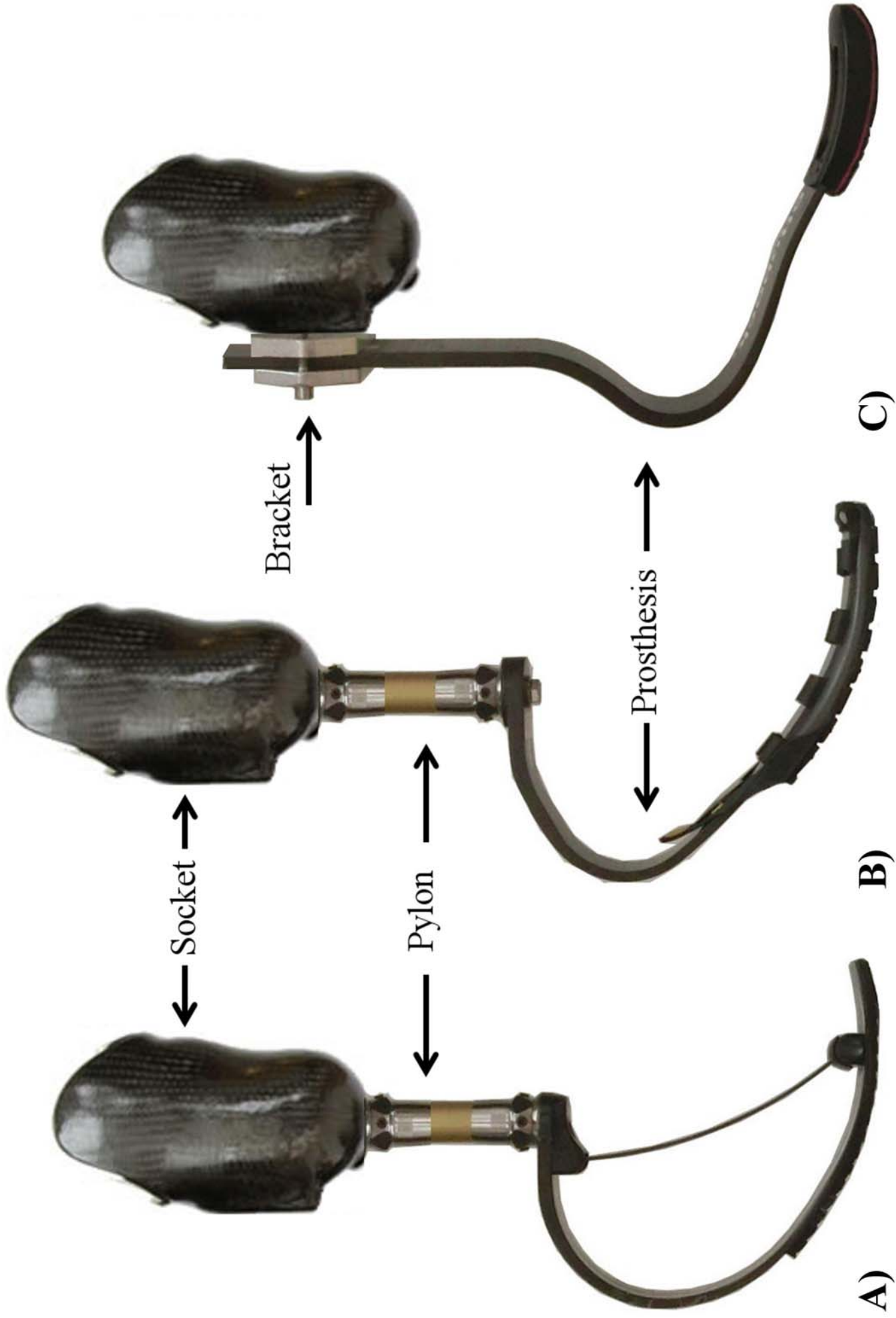
**Table 1.** Average ( $\pm$ SD) anthropometric measurements and standing metabolic rates of athletes with unilateral transtibial amputations (7M, 3F). \*indicates a significant difference between recommended (Rec) affected leg (AL) and unaffected leg (UL) lengths ( $p < 0.05$ ), following a Bonferroni corrected paired two-tailed t-test.

**Table 2.** The number of participants for each prosthetic model, at recommended (Rec) and  $\pm 1$  stiffness categories, and Rec and  $\pm 2$  cm height (Ht) configurations.

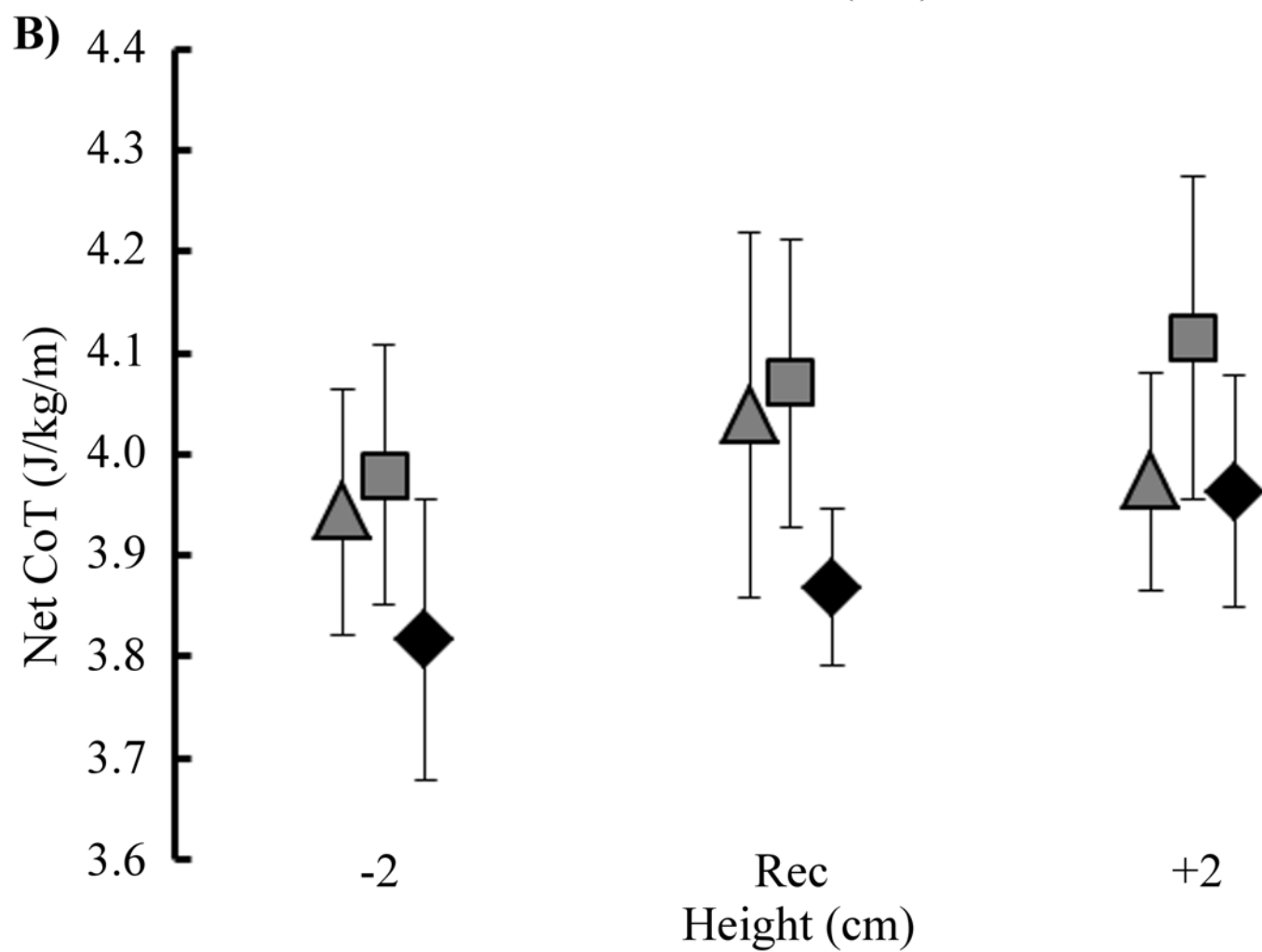
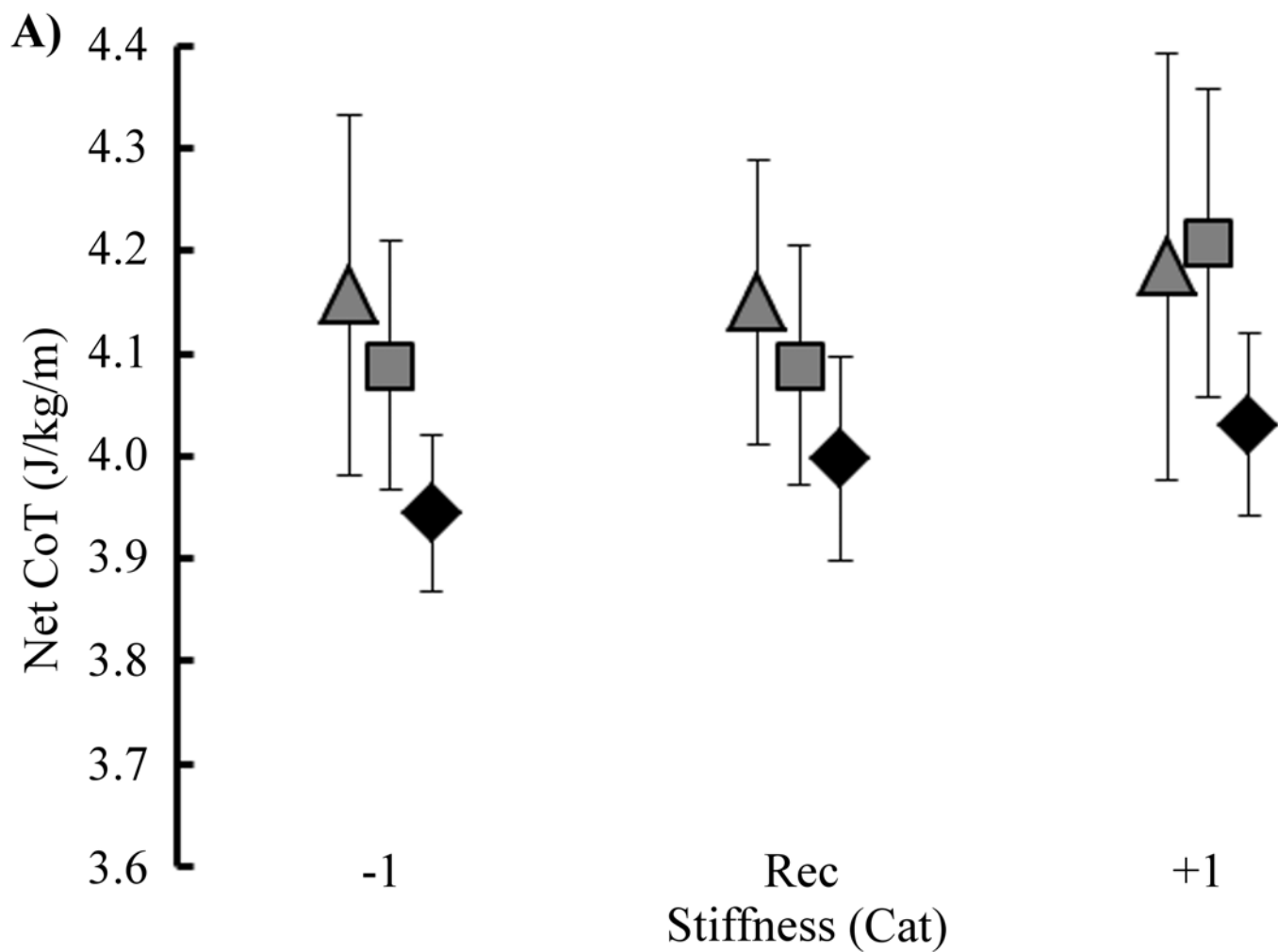
**Table 3.** The biomechanical variables that influenced net CoT: overall peak vertical ground reaction force (vGRF), stance average vGRF (Avg vGRF), ground contact time ( $t_c$ ), leg stiffness ( $k_{leg}$ ), and peak vGRF asymmetry at each stiffness category (Recommended (Rec) and  $\pm 1$  category) for each prosthetic model at the recommended height. “BW” indicates bodyweight, and “SI” indicates symmetry index as a percent. \* indicates significant effect of prosthetic stiffness (kN/m) on the biomechanical variable across all of our data using linear mixed model analyses.

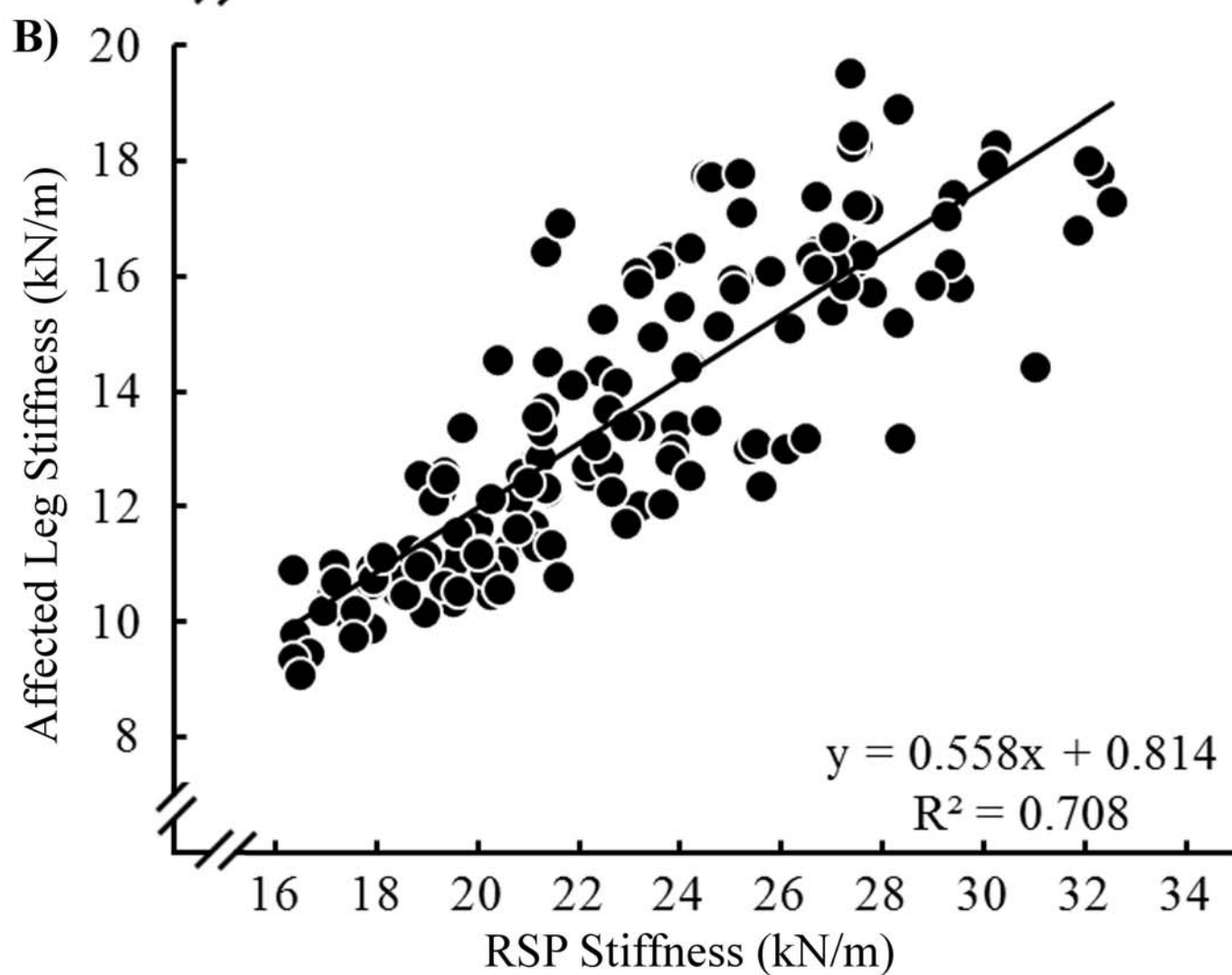
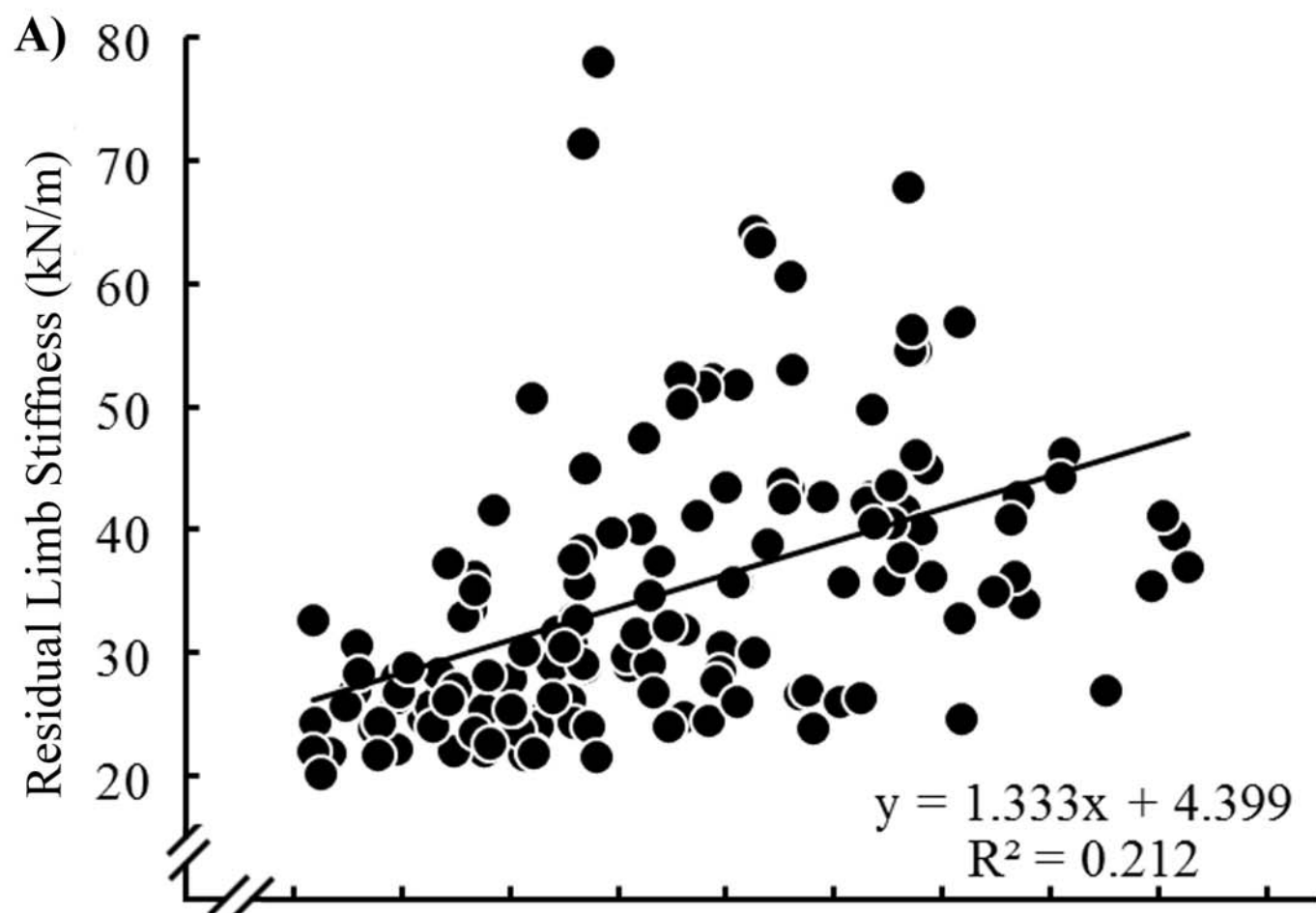
**Table 4.** The biomechanical variables that influenced net CoT: overall peak vertical ground reaction force (vGRF), stance average vGRF (Avg vGRF), ground contact time ( $t_c$ ), leg stiffness ( $k_{leg}$ ), and peak vGRF asymmetry at each prosthetic height (Ht) (Recommended (Rec) and  $\pm 2$  cm) for every prosthetic model across stiffness categories. “BW” indicates bodyweight, and “SI” indicates symmetry index. \* indicates significant effect of prosthetic height on biomechanical variable across all of our data using linear mixed model analyses.

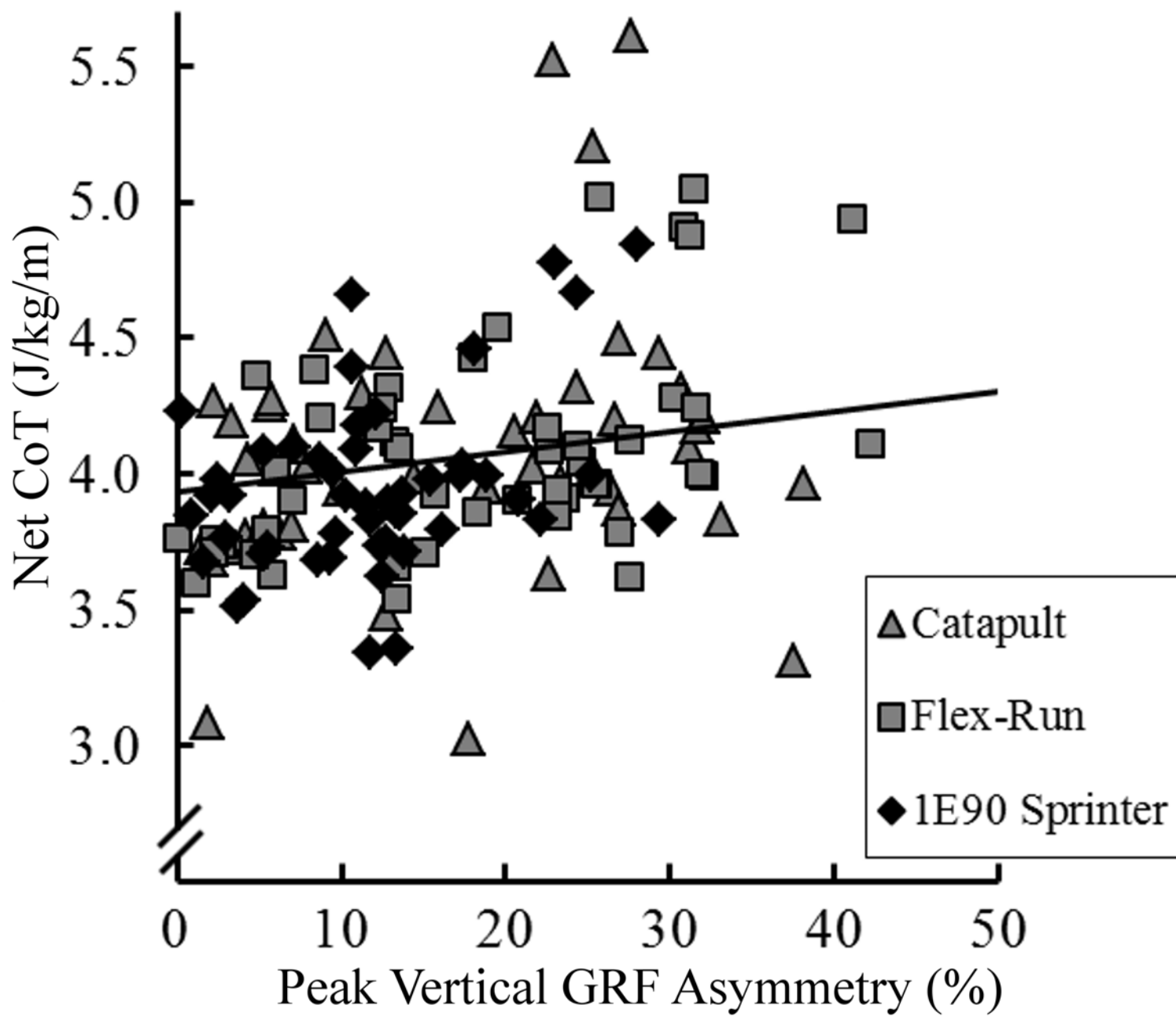


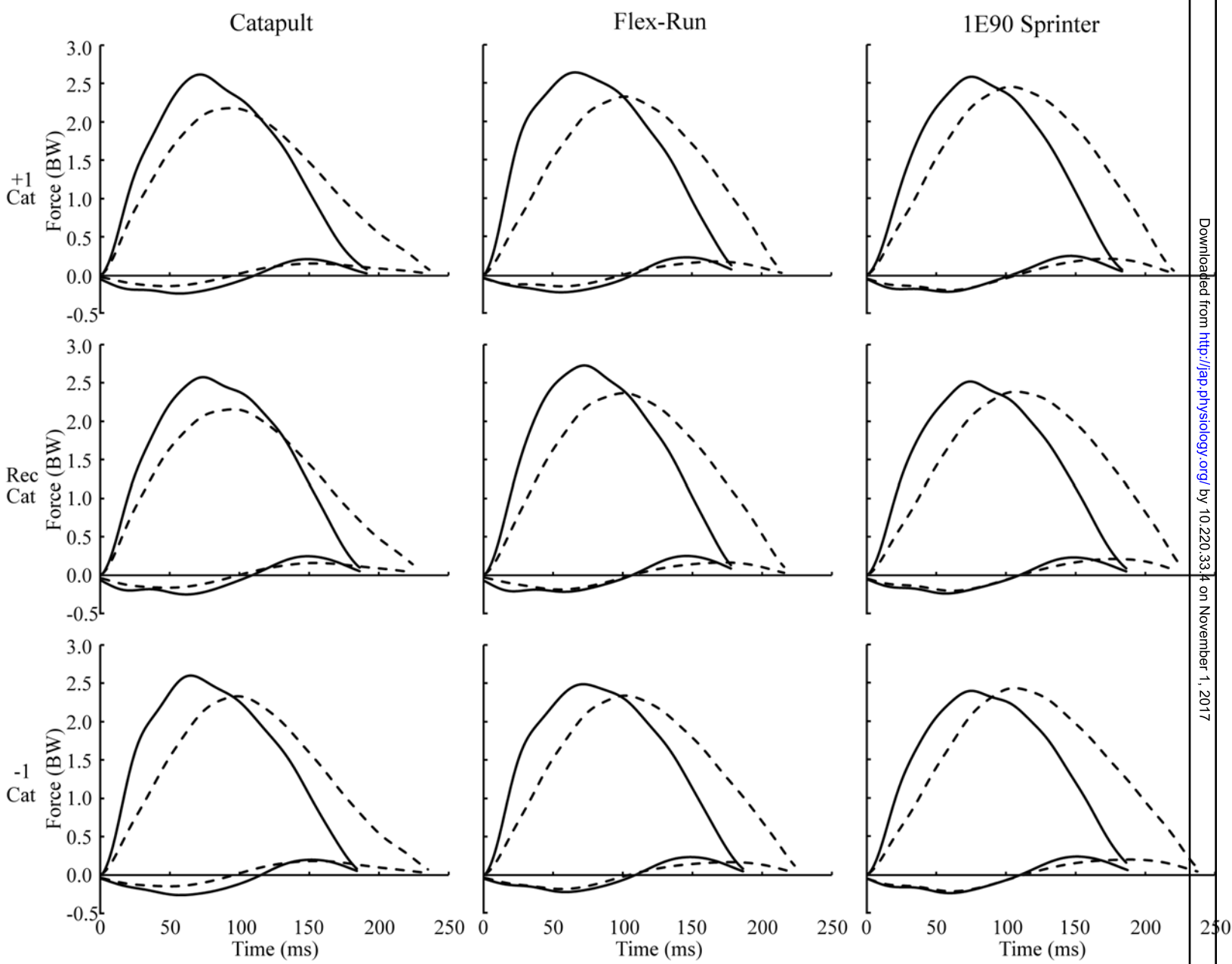




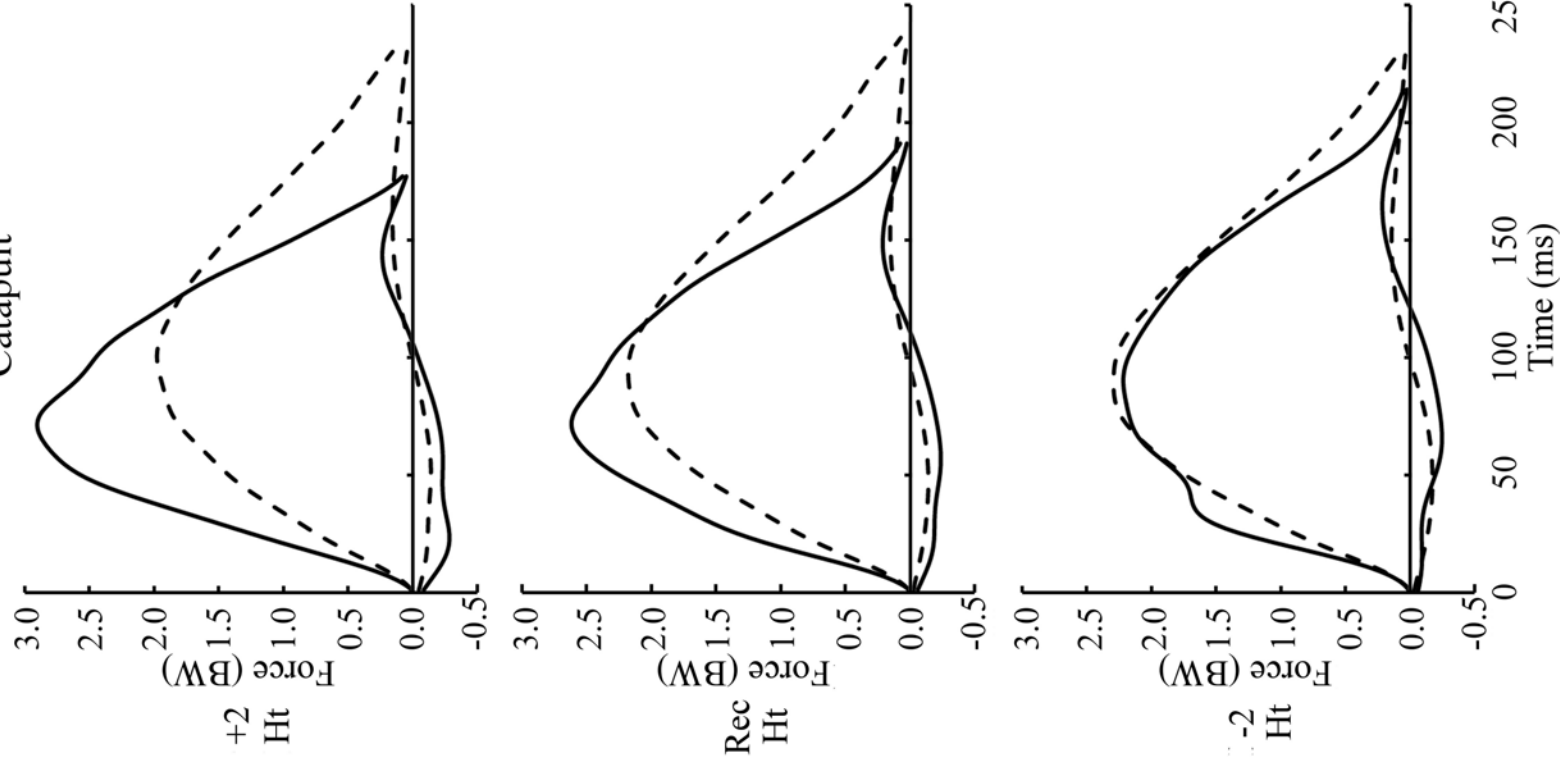




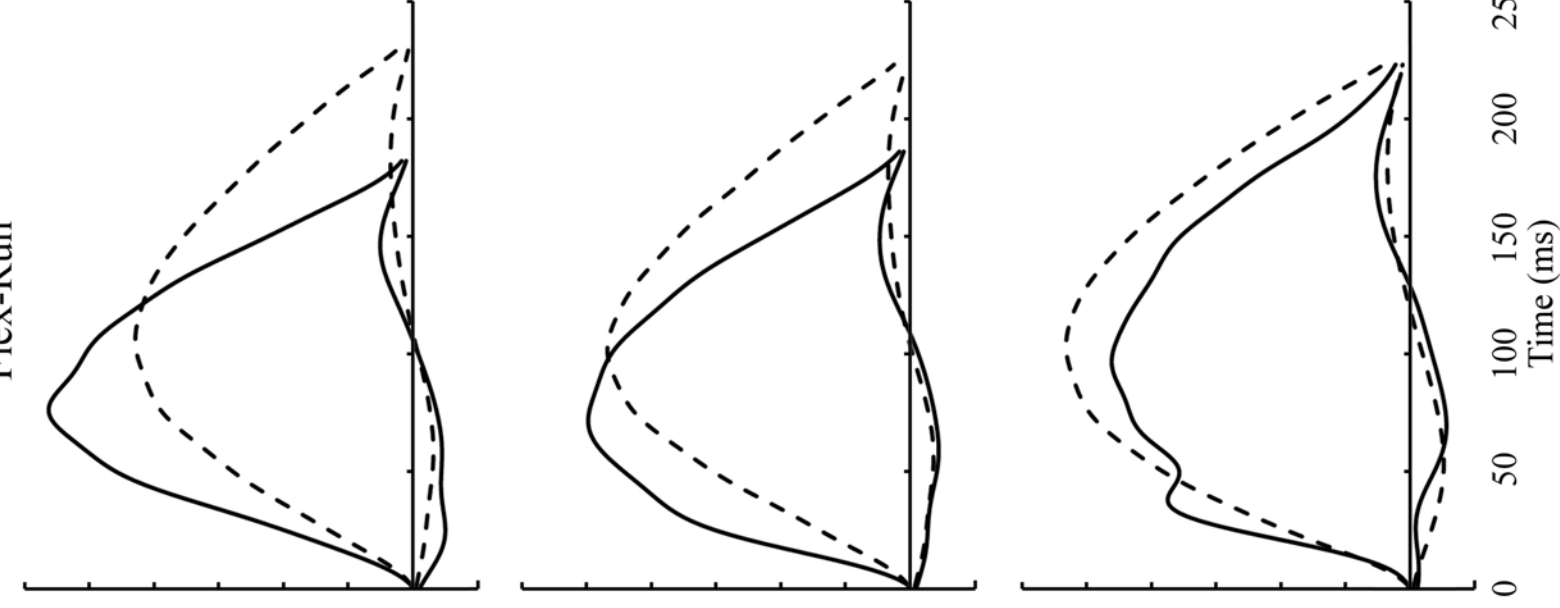




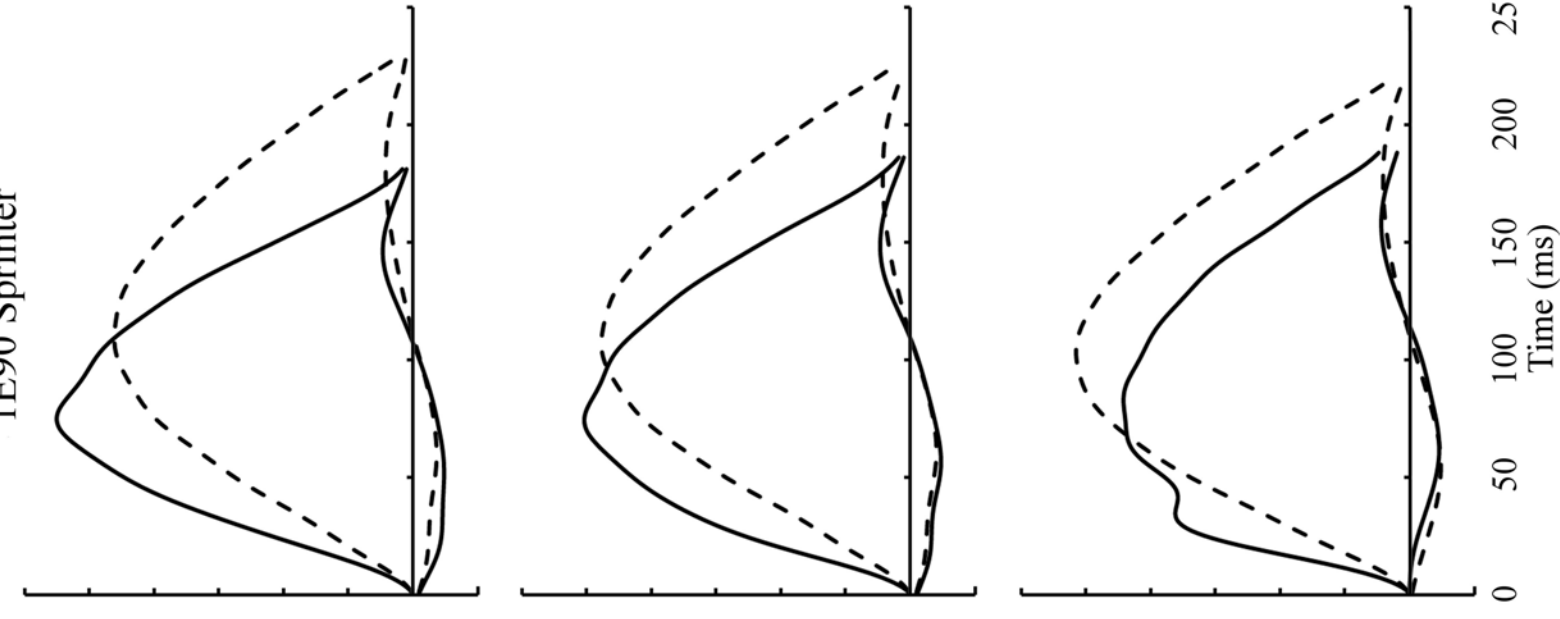
Catapult



Flex-Run



1E90 Sprinter



Age	$33.4 \pm 6.1$ yrs
Height	$1.77 \pm 0.08$ m
Body mass	$76.1 \pm 14.1$ kg
UL leg length	$0.95 \pm 0.05$ m
Rec Catapult AL length	$1.01 \pm 0.07$ m*
Rec Flex-Run AL length	$1.00 \pm 0.07$ m*
Rec 1E90 Sprinter AL length	$0.98 \pm 0.07$ m
Standing metabolic rate	$1.3 \pm 0.1$ W/kg

		Catapult			Flex-Run			1E90 Sprinter		
		-1 Cat	Rec Cat	+1 Cat	-1 Cat	Rec Cat	+1 Cat	-1 Cat	Rec Cat	+1 Cat
Number of Participants	+2 cm	5	2	2	4	5	1	5	2	2
	Rec Ht	10	10	10	10	10	8	10	10	10
	-2 cm	5	2	2	4	4	1	6	2	2

	Catapult			Flex-Run			1E90 Sprinter		
Biomechanics	-1 Cat	Rec Cat	+1 Cat	-1 Cat	Rec Cat	+1 Cat	-1 Cat	Rec Cat	+1 Cat
Peak vGRF (BW)	2.40	2.39	2.40	2.38	2.40	2.43	2.37	2.37	2.40
Avg vGRF (BW)*	1.32	1.34	1.35	1.38	1.39	1.41	1.34	1.35	1.39
t <sub>c</sub> (sec)*	0.27	0.26	0.25	0.25	0.25	0.24	0.27	0.26	0.25
k <sub>leg</sub> (kN/m)*	14.0	14.4	15.0	14.3	14.5	14.3	13.2	13.6	14.5
Peak vGRF (SI)	15.0	18.4	18.8	14.6	16.9	17.6	9.2	10.3	13.1



	Catapult			Flex-Run			1E90 Sprinter		
Biomechanics	-2 cm	Rec Ht	+2 cm	-2 cm	Rec Ht	+2 cm	-2 cm	Rec Ht	+2 cm
Peak vGRF (BW)	2.40	2.40	2.36	2.51	2.38	2.37	2.35	2.38	2.38
Avg vGRF (BW)	1.33	1.33	1.30	1.45	1.38	1.36	1.33	1.36	1.34
t <sub>c</sub> (sec)	0.26	0.26	0.27	0.25	0.25	0.26	0.27	0.26	0.27
k <sub>leg</sub> (kN/m)	14.6	14.4	14.3	15.3	14.5	14.4	13.2	13.8	13.4
Peak vGRF (SI)*	8.8	17.4	23.8	13.8	16.6	27.1	8.9	10.8	19.0

## RESEARCH ARTICLE

# Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations

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<sup>1</sup>Department of Integrative Physiology, University of Colorado, Boulder, Colorado; and <sup>2</sup>Department of Veterans Affairs, Eastern Colorado Healthcare System, Denver, Colorado

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**Beck ON, Taboga P, Grabowski AM.** Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. *J Appl Physiol* 122: 976–984, 2017. First published January 19, 2017; doi:10.1152/jappphysiol.00587.2016.— Inspired by the springlike action of biological legs, running-specific prostheses are designed to enable athletes with lower-limb amputations to run. However, manufacturer's recommendations for prosthetic stiffness and height may not optimize running performance. Therefore, we investigated the effects of using different prosthetic configurations on the metabolic cost and biomechanics of running. Five athletes with bilateral transtibial amputations each performed 15 trials on a force-measuring treadmill at 2.5 or 3.0 m/s. Athletes ran using each of 3 different prosthetic models (Freedom Innovations Catapult FX6, Össur Flex-Run, and Ottobock 1E90 Sprinter) with 5 combinations of stiffness categories (manufacturer's recommended and  $\pm 1$ ) and heights (International Paralympic Committee's maximum competition height and  $\pm 2$  cm) while we measured metabolic rates and ground reaction forces. Overall, prosthetic stiffness [fixed effect ( $\beta$ ) = 0.036;  $P$  = 0.008] but not height ( $P \geq 0.089$ ) affected the net metabolic cost of transport; less stiff prostheses reduced metabolic cost. While controlling for prosthetic stiffness (in kilonewtons per meter), using the Flex-Run ( $\beta$  = -0.139;  $P$  = 0.044) and 1E90 Sprinter prostheses ( $\beta$  = -0.176;  $P$  = 0.009) reduced net metabolic costs by 4.3–4.9% compared with using the Catapult prostheses. The metabolic cost of running improved when athletes used prosthetic configurations that decreased peak horizontal braking ground reaction forces ( $\beta$  = 2.786;  $P$  = 0.001), stride frequencies ( $\beta$  = 0.911;  $P$  < 0.001), and leg stiffness values ( $\beta$  = 0.053;  $P$  = 0.009). Remarkably, athletes did not maintain overall leg stiffness across prosthetic stiffness conditions. Rather, the in-series prosthetic stiffness governed overall leg stiffness. The metabolic cost of running in athletes with bilateral transtibial amputations is influenced by prosthetic model and stiffness but not height.

**NEW & NOTEWORTHY** We measured the metabolic rates and biomechanics of five athletes with bilateral transtibial amputations while running with different prosthetic configurations. The metabolic cost of running for these athletes is minimized by using an optimal prosthetic model and reducing prosthetic stiffness. The metabolic cost of running was independent of prosthetic height, suggesting that longer legs are not advantageous for distance running. Moreover, the in-series prosthetic stiffness governs the leg stiffness of athletes with bilateral leg amputations.

amputee; prosthesis; biomechanics; prescription; economy

RUNNING IS A BOUNCING GAIT that is mechanically well-characterized by a spring-mass model, which depicts the stance leg as a massless linear spring and the body as a point mass (Fig. 1; Refs. 15, 25, 47). In the model, the leg spring compresses and stores elastic energy during the first half of the stance phase. Subsequently, the leg spring releases energy as it lengthens from midstance through the end of ground contact (5). During running, elastic elements such as tendons and ligaments act as springs that stretch and recoil (5, 12, 38, 55). Inspired by the springlike action of biological legs, passive-elastic carbon-fiber running-specific prostheses (RSPs) are designed to enable athletes with lower-limb amputations to run. RSPs are shaped like the uppercase letters “C” or “J,” attach in-series to residual limbs (Fig. 2), and emulate the springlike function of biological legs during level-ground running (5, 12, 38, 55) by storing and returning elastic energy during ground contact (11, 18, 51). Since conserving mechanical energy via elastic mechanisms theoretically reduces the metabolic cost of running (5, 12, 38, 55), the elastic function of RSPs likely contributes to the 14% lower metabolic cost of running for athletes with transtibial amputations using RSPs compared with using relatively rigid, conventional walking prostheses (17).

Despite reducing the metabolic cost of running (17) and improving athletic performances compared with the use of previous prosthetic designs (34), current manufacturer's recommendations for prosthetic stiffness may not optimize the running performance of athletes with bilateral transtibial amputations. For athletes with unilateral amputations, the aim of the current manufacturer's recommended prosthetic configurations is to mitigate stride kinematic asymmetries between the affected and unaffected legs (e.g., asymmetric ground contact times; Ref. 51a). For athletes with bilateral amputations, prosthetists simply match the left- and right-leg RSPs at the manufacturer's recommended stiffness category, which is based on the same prosthetic-stiffness-to-body-mass ratio as athletes with unilateral amputations (30a, 51a, 51b).

Surface stiffness, which is in-series with the stance leg, affects the running performance of nonamputees (39, 47). For example, Kerdok et al. (39) reported that changing surface stiffness from 945 to 75 kN/m decreased the metabolic cost of running in nonamputees by 12%. This decreased metabolic cost was primarily attributed to the greater mechanical energy return from the compliant surface to the runner. Furthermore, when surface compliance changes, nonamputees maintain a constant overall surface plus leg stiffness by altering leg joint stiffness and/or segment geometries during running (29, 30, 39). Straighter limb posture generally results in lower joint

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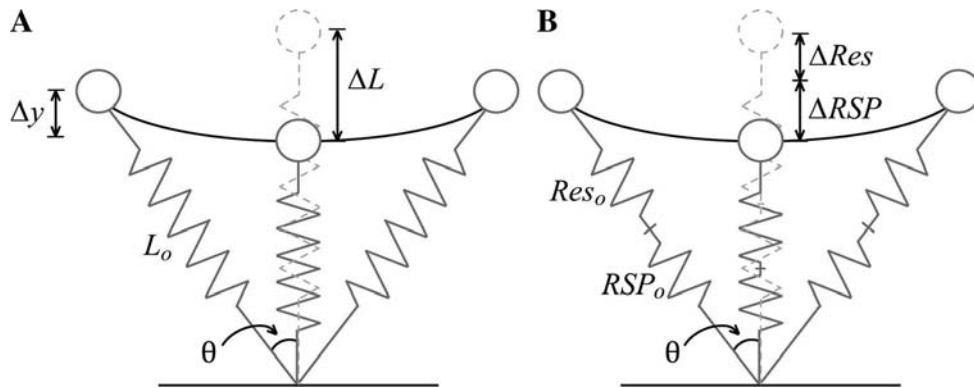


Fig. 1. Illustration of a spring-mass model of running (A) and a spring-mass model of running with an in-series leg spring (B). Body mass is represented as a point mass (circle), and the touch-down angle is indicated by  $\theta$ . The stance leg is represented by a massless linear spring for nonamputees (A) or 2 in-series massless linear springs for athletes with bilateral amputations (B). The initial leg length ( $L_0$ ) shortens ( $\Delta L$ ) as does its vertical height ( $\Delta y$ ) during the stance phase of running. Modeled residual limb length ( $Res_0$ ) and prosthetic height ( $RSP_0$ ) compress and extend ( $\Delta Res$  and  $\Delta RSP$ ) during the stance phase of running.

moments and in turn reduces the muscular force needed to support body weight (13, 14), which is the primary determinant of the metabolic cost of running (9, 40, 41, 43, 53). These previous studies suggest that decreasing prosthetic stiffness will reduce the metabolic cost of running. However, the effects of prosthetic stiffness on overall leg stiffness and metabolic cost during running have yet to be determined.

Analogous to prosthetic stiffness recommendations, current prosthetic height recommendations may not optimize distance running performance. Prosthetic height is set at the discretion of the athlete and/or their prosthetist and/or in accordance with the International Paralympic Committee (IPC) guidelines (37a). Anecdotally, the potential effects of increased prosthetic height were brought to light at the 2012 Paralympic Games when it appeared that athletes with bilateral transtibial amputations improved their sprinting performance by using taller RSPs. Hypothetically, longer legs could improve running speed by increasing the forward distance traveled during ground contact while accounting for step frequency and the stance average vertical ground reaction force (GRF; Ref. 58). Previous research indicates that the metabolic cost of running is poorly associated with the leg lengths of nonamputees (60); however, simple correlations fail to account for potential co-

variates such as increased lower limb mass with longer legs. No study has systemically altered prosthetic height for athletes with bilateral leg amputations and assessed its influence on distance running performance.

We sought to determine how the use of RSPs with different stiffness values and heights affect the metabolic cost of running for athletes with bilateral transtibial amputations. Since reduced prosthetic stiffness may enhance mechanical energy conservation and improve the effective mechanical advantage of the stance leg, we hypothesized that using RSPs with a lower stiffness than manufacturer recommended would decrease the metabolic cost of running. Given the lack of previous data, we tested the null hypothesis that altering prosthetic height would not affect the metabolic cost of running. Based on several studies (29, 30, 39), we hypothesized that residual limb stiffness (comprising knee and hip joints) would be inversely associated with prosthetic stiffness such that athletes would maintain overall leg stiffness across different prosthetic stiffness configurations.

Finally, the metabolic cost of running is often associated with biomechanical variables such as vertical (41, 43, 56) and horizontal GRF magnitude (9, 24), ground contact time (41, 43), stride frequency (23, 35), and leg stiffness (23, 26, 35). For those reasons, we sought to quantify how the metabolic cost of running relates to these biomechanical variables in athletes with bilateral transtibial amputations.

## METHODS

**Subjects.** Five male athletes with bilateral transtibial amputations participated (Table 1). Each athlete had over one year of experience using RSPs, which included track and field races. The protocol was approved by the Colorado Multiple Institutional Review Board and the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections, Human Research Protection Office, and before participation each athlete gave informed written consent in accordance with our protocol.

**Protocol.** Initially, each participant completed a fitting and accommodation session. During this session, we collected anthropometric measurements to determine the tallest height that each participant could use to compete in track and field races according to the IPC guidelines (37a). Next, a certified prosthetist fit each participant with three different prosthetic models (Freedom Innovations Catapult FX6, Irvine, CA; Össur Flex-Run, Reykjavik, Iceland; and Ottobock 1E90 Sprinter, Duderstadt, Germany) at the manufacturer's recommended stiffness category and  $\pm 1$  stiffness categories and at leg lengths that produced the IPC maximum competition height and  $\pm 2$  cm. Prosthetic stiffness categories are recommended to athletes based on user

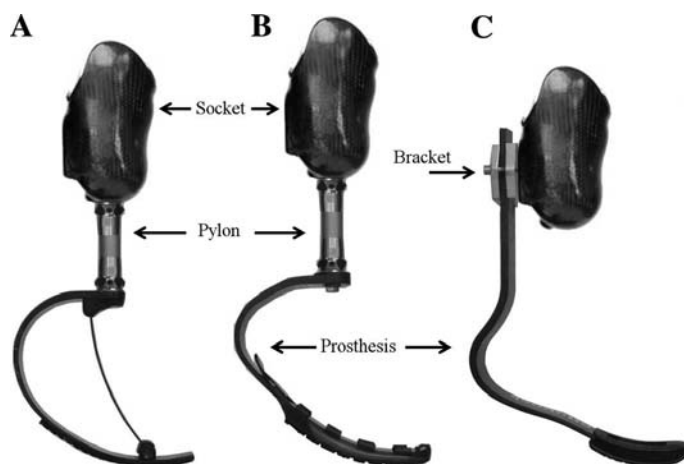


Fig. 2. From left to right: A, the Freedom Innovations Catapult FX6 prosthesis (C-shaped) at a representative recommended height; B, the Össur Flex-Run prosthesis (C-shaped) at a representative height of +2 cm; and C, the Ottobock 1E90 Sprinter prosthesis (J-shaped) at a representative height of -2 cm. The C-shaped prostheses are connected to sockets via aluminum pylons, and the J-shaped prostheses are connected to sockets via custom aluminum brackets.



Table 1. Participant characteristics: age, mass, average standing metabolic power, cause of amputations, primary event(s), standing height, and leg length

Participants	Age, yr	Mass, kg	Standing Metabolic Power, W/kg	Cause of Amputations	Primary Event	Max IPC Height, m	Max IPC Leg Length, m	Catapult Leg Length, m	Flex-Run Leg Length, m	1E90 Sprinter Leg Length, m
1	25	69.8	1.6	Congenital	100/200 m	1.80	0.97	1.12	1.12	0.97
2	23	76.1	1.5	Congenital	Long jump	1.88	1.07	1.07	1.07	1.04
3	18	73.2	1.7	Congenital	100/200 m	1.87	1.05	1.05	1.05	1.05
4	31	69.6	1.3	Traumatic	400 m	1.90	1.10	1.10	1.10	1.10
5	27	68.9	1.5	Infection	5,000 m	1.87	1.06	1.06	1.06	1.06
Average	24.8	71.5	1.5			1.86	1.05	1.08	1.08	1.04
SD	4.8	3.0	0.2			0.04	0.05	0.03	0.03	0.04

The maximum standing height and corresponding leg lengths allowed in track and field races sanctioned by the International Paralympic Committee (IPC; Ref. 37a). The resulting Catapult, Flex-Run, and 1E90 Sprinter prosthesis leg lengths represent the closest attainable maximum IPC-regulated leg lengths from each participant and prosthetic model combination (37a). Leg lengths were measured from the greater trochanters to the most distal locations of the unloaded prostheses.

body mass with larger athletes recommended numerically greater stiffness categories (30a, 51a, 51b). The Catapult and Flex-Run prostheses are shaped like a “C” and attach distally to the sockets that encompass the residual limbs, via connective aluminum pylons (Fig. 2). The 1E90 Sprinter prostheses are shaped like a “J” and mount to the posterior wall of each socket (Fig. 2). After establishing the heights for J-shaped RSPs, they are typically bolted directly to the sockets. Instead, we constructed custom aluminum brackets that were bolted to the sockets, thus allowing us to preserve the RSPs, secure them to the sockets, and alter height between trials (Fig. 2). Sockets are carbon-fiber or fiber-glass (check sockets) negative composites of a residual limb and are secured to the limb via suction or locking mechanisms.

Because of the combined lengths of the participant's residual legs and the heights of prosthetic components, we were unable to match the maximum IPC competition height for some participants with certain prosthetic models. The build height of C-shaped RSPs limit the minimum participant height (Fig. 2). For example, the minimum height of the Flex-Run prosthesis is 277 mm before adding the components necessary for socket attachment (51a). Thus, if the maximum IPC competition height for a participant is less than the length from the top of their head to the end of their residual limb plus 277 mm, they will exceed the maximum IPC height with the respective prosthetic model under all conditions. Also, the maximum achievable height was limited while using J-shaped RSPs. The 1E90 Sprinter prostheses could not exceed their build height; consequently, a participant with short residual limbs was unable reach the maximum IPC height using the 1E90 Sprinter prostheses (Table 1), whereas the C-shaped RSPs could be made as tall as necessary through the use of connective pylons. For these cases, we set prosthetic height as close as feasible to the maximum IPC competition height. If the closest achievable height was taller than the maximum IPC competition height, ensuing prosthetic height alterations were +2 and +4 cm. If the closest achievable height was shorter than the maximum IPC competition height, ensuing prosthetic height alterations were −2 and −4 cm (Table 1).

After being fit with different prosthetic configurations, participants ran on a treadmill at self-selected speeds until both the prosthetist and participant were satisfied. Generally, athletes were accommodated to each prosthetic model at the recommended stiffness category and height. When using C-shaped RSPs, athletes also ran at additional heights (i.e.,  $\pm 2$  cm) to determine proper alignment with taller/shorter pylons. When using J-shaped RSPs, the components and alignment were the same for each height; thus athletes were not typically accommodated to additional heights. The accommodation sessions lasted approximately 6–7 h per participant. All participants used their personal competition sockets for the trials with the respective prosthetic shape (4 used J-shaped and 1 used C-shaped RSPs). The 4 athletes who competed with J-shaped RSPs used their everyday

walking sockets for the C-shaped RSP trials. For the athlete who competed with C-shaped RSPs, a prosthetist fabricated custom check sockets that replicated the participant's competition sockets (suspension, internal dimensions, et cetera) for the J-shaped RSP trials.

On subsequent days, participants performed a 5-min standing trial (using their personal walking prostheses) and up to 6 5-min running trials per session with at least 5 min of rest between trials. The combination of the rest periods and the moderate-intensity running trials adequately prevented any potential effects of fatigue. For example, previous studies reported that subjects who run at a moderate intensity for trial lengths up to 7 min display no signs of fatigue (31, 32).

Participants ran on a 3-dimensional force-measuring treadmill (Treadmetrix, Park City, UT) at 3 m/s. If a participant was unable to maintain primarily oxidative metabolism at 3 m/s, as indicated by a respiratory exchange ratio  $>1.0$ , running speed was set to 2.5 m/s for all of their respective trials. Each participant ran using 15 different prosthetic model, stiffness category, and height combinations. Initially, participants ran using each prosthetic model at 3 stiffness categories (recommended and  $\pm 1$ ) and the maximum competition height. The stiffness category for each prosthetic model that elicited the lowest net metabolic cost of transport (CoT in joules per kilogram per meter) was deemed optimal. Subsequently, participants ran using the optimal stiffness category of each prosthetic model at 2 additional heights (e.g.,  $\pm 2$  cm). We randomized the trial order beginning with the 9 prosthetic model and stiffness category combinations at the maximum IPC height. Once a participant completed trials in all 3 stiffness categories with a prosthetic model, the altered height trials for the respective model at the optimal stiffness category were randomly inserted into the trial order. Data were collected over 3–5 sessions, and all participants completed the protocol within 9 days following the accommodation session.

**Metabolic cost of transport.** We instructed participants to fast for at least 3 h before testing. We measured their rates of oxygen consumption ( $\dot{V}O_2$ ) and carbon dioxide production ( $\dot{V}CO_2$ ) using open-circuit expired gas analysis (TrueOne 2400; Parvo Medics, Sandy, UT) throughout each trial and averaged these rates during the last 2 min of each trial to calculate steady-state metabolic rates. We used the Brockway equation (16) to convert the average  $\dot{V}O_2$  and  $\dot{V}CO_2$  into metabolic power. Then, we subtracted the average metabolic power consumed during standing of the corresponding day from each running trial to yield net metabolic power. We normalized net metabolic power by the mass of the participant for each prosthetic condition. Participant mass included running gear. Finally, to compare 3.0 and 2.5 m/s trials, we divided net metabolic power by running velocity to calculate the net metabolic cost of transport (CoT) in joules per kilogram per meter. We tested each participant at the same time of day for all of their respective sessions.

**Prosthetic stiffness.** Recommended prosthetic stiffness (in kilonewtons per meter) differs between models (11). Therefore, we assessed the influence of the manufacturer's recommended prosthetic stiffness category as well as actual prosthetic stiffness (in kilonewtons per meter) on the net CoT during running (11) using established data. We calculated prosthetic stiffness from the mean peak vertical GRF measured from both legs during each trial (present study) and the force-displacement equations from Ref. 11 to estimate prosthetic displacement. Subsequently, we divided the measured peak vertical GRF magnitude by the estimated prosthetic displacement to yield stiffness.

**Biomechanics.** We measured vertical and anterior-posterior components of the ground reaction forces (GRFs) between *minutes 2.0* and *3.0* and *minutes 3.5* and *5.0* of each trial. We collected GRFs at 1,000 Hz, filtered them using a 4th-order low-pass Butterworth filter with a 30-Hz cutoff frequency, and then used filtered data to calculate GRF parameters, stride kinematics, and leg stiffness values from 10 consecutive strides (20 steps) with a custom MATLAB script (The MathWorks, Natick, MA). We set our GRF threshold at 1% of user body weight to detect periods of ground contact.

We calculated overall leg stiffness ( $k_{\text{leg}}$ ) as the quotient of peak vertical GRF ( $F_{\text{peak}}$ ) and maximum leg spring compression ( $\Delta L$ ) during ground contact (Fig. 1; Ref. 25):

$$k_{\text{leg}} = \frac{F_{\text{peak}}}{\Delta L}. \quad (1)$$

To calculate the maximum compression of the leg spring ( $\Delta L$ ), we measured initial leg length ( $L_0$ ) as the distance from the greater trochanter to the distal end of the unloaded RSP (33, 46). Next, we used initial leg lengths to calculate  $\theta$ , which is the angle of the leg spring at initial ground contact relative to vertical (Fig. 1), using Eq. 2.

$$\theta = \sin^{-1} \left( \frac{vt_c}{2L_0} \right). \quad (2)$$

Because the spring-mass model assumes step symmetry about the vertical axis (15, 25, 47),  $\theta$  equals half of the angle swept by the stance leg, as determined from running velocity ( $v$ ), ground contact time ( $t_c$ ), and initial leg length ( $L_0$ ). The maximum stance leg spring compression ( $\Delta L$ ) was calculated using Eq. 3:

$$\Delta L = \Delta y + L_0(1 - \cos\theta), \quad (3)$$

which incorporates peak vertical displacement of the center of mass during ground contact ( $\Delta y$ ), calculated by twice integrating the vertical acceleration of the center of mass with respect to time (19). The instantaneous vertical acceleration of the center of mass was calculated by subtracting the participant's body weight from the vertical GRF magnitude (net force) and dividing by body mass (19).

Since biological legs and RSPs have relatively linear force-displacement profiles (11, 25), we modeled overall leg stiffness ( $k_{\text{leg}}$ ) as two in-series springs (Fig. 1). We used previously established measurements of prosthetic stiffness ( $k_{\text{RSP}}$ ; Ref. 11) to estimate residual limb stiffness ( $k_{\text{res}}$ ) using Eq. 4.

$$\frac{1}{k_{\text{leg}}} = \frac{1}{k_{\text{res}}} + \frac{1}{k_{\text{RSP}}}. \quad (4)$$

Because of the potential association between the mechanical energy delivered by the RSPs and the metabolic cost of running, we calculated mechanical power return from the RSPs for each step ( $\dot{P}_{\text{RSP}}$ ):

$$\dot{P}_{\text{RSP}} = \frac{k_{\text{RSP}}(\Delta d)^2(1 - \text{Hst}_{\text{RSP}}/100)}{2t_{\text{step}}}, \quad (5)$$

determined by prosthetic stiffness ( $k_{\text{RSP}}$ ), peak prosthetic displacement ( $\Delta d$ ), percentage prosthetic hysteresis ( $\text{Hst}_{\text{RSP}}$ ; Ref. 11), and step

time ( $t_{\text{step}}$ ). To relate prosthetic mechanical energy return to metabolic cost of transport (in joules per kilogram per meter), we divided the energy return averaged per step by user body mass ( $m$ ) and running velocity ( $v$ ) to calculate mechanical energy return ( $\dot{E}_{\text{RSP}}$ ) in joules per kilogram per meter:

$$\dot{E}_{\text{RSP}} = \frac{\dot{P}_{\text{RSP}}}{mv}. \quad (6)$$

**Statistical analyses.** We used a linear mixed model to evaluate the effects of using different prosthetic models, stiffness categories, and heights on net CoT. We used a second linear mixed model with actual prosthetic stiffness (in kilonewtons per meter) instead of stiffness category to evaluate the effects of using different prosthetic models, stiffness, and heights on net CoT.

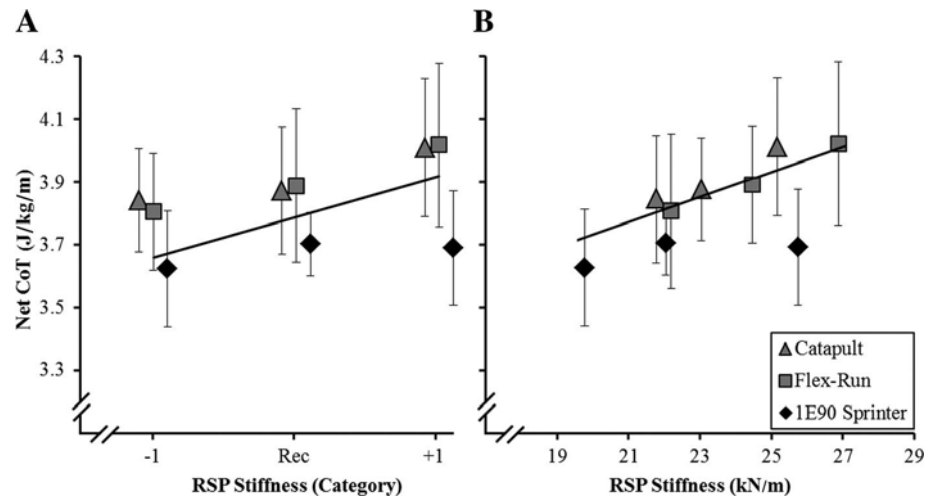
Three of our participants ran at 3.0 m/s, and two ran at 2.5 m/s. Accordingly, we used linear mixed models to control for speed while independently testing the associations of the predetermined GRF parameters (stance average vertical GRF, peak vertical GRF, and peak horizontal braking and propulsive GRFs), stride kinematics (ground contact time and stride frequency), and leg stiffness on the net CoT. To evaluate the influence of prosthetic mechanical energy return on net CoT, in addition to the relationships between leg stiffness, prosthetic stiffness, and residual limb stiffness, we performed simple linear regressions. We performed paired two-tailed *t*-tests to compare each biomechanical variable from *minutes 2.0* to *3.0* to the respective variable from *minutes 3.5* to *5.0* to ensure participants achieved a biomechanical steady-state. We reported the fixed effect ( $\beta$ ) from each statistically significant association (dependent variable =  $\beta$  independent variable + intercept). When appropriate, we implemented a Bonferroni correction and tested for potential interaction effects across all statistical comparisons. We set the level of significance at  $\alpha = 0.05$  and performed statistical analyses using RStudio software (Boston, MA).

## RESULTS

While controlling for covariates, use of different prosthetic stiffness (category and in kilonewtons per meter;  $P \leq 0.008$ ; Fig. 3), but not height ( $P \geq 0.089$ ; Fig. 4), affected the net CoT of athletes with bilateral transtibial amputations. Each integer reduction in stiffness category decreased the average net CoT by 3.7% ( $\beta = 0.135$ ;  $P < 0.001$ ). Actual prosthetic stiffness values ranged from 19.3 to 29.6 kN/m and averaged  $22.9 \pm 2.3$  kN/m ( $\pm$ SD). Overall, every 1 kN/m reduction in prosthetic stiffness decreased net CoT by 1.3% ( $\beta = 0.036$ ;  $P = 0.008$ ; Fig. 3).

The metabolic cost of running was associated with the equipped prosthetic model. The influence of prosthetic model on net CoT was largely the same when controlling for either prosthetic stiffness category or actual stiffness (in kilonewtons per meter), thus unless otherwise specified, we will interpret prosthetic model effects while controlling for actual prosthetic stiffness (in kilonewtons per meter). Within our prosthetic stiffness range, when athletes with bilateral transtibial amputations used the 1E90 Sprinter prostheses, their net CoT was 4.3–4.7% lower compared with using Catapult prostheses ( $\beta = -0.176$ ;  $P = 0.009$ ). The net CoT was similar when athletes used the Flex-Run vs. 1E90 Sprinter prostheses ( $P = 0.597$ ). When controlling for stiffness category, the use of Flex-Run prostheses elicited similar net CoT values compared with the use of Catapult prostheses ( $P = 0.138$ ), whereas while controlling for actual prosthetic stiffness (in kilonewtons per

Fig. 3. A: mean ( $\pm$ SE) net metabolic cost of transport (CoT) as a function of using different models of running-specific prostheses (RSPs) with different stiffness categories (Cat). Symbols are offset for clarity. Regression equation: net CoT =  $0.129 \Delta \text{Cat} + 3.786$ . Rec, recommended stiffness. B: mean ( $\pm$ SE) net metabolic cost of transport (CoT) as a function of actual prosthetic stiffness (in kilonewtons per meter) across prosthetic models. Regression equation: net CoT =  $0.036 \Delta \text{kN/m} + 2.931$ . Triangles represent use of the C-shaped Catapult, squares represent use of the C-shaped Flex-Run, and diamonds represent use of the J-shaped 1E90 Sprinter prostheses.



meter), the use of Flex-Run prostheses reduced net CoT 4.4–4.9% compared with the use of Catapult prostheses ( $\beta = -0.139$ ;  $P = 0.044$ ), highlighting the dissimilarity in manufacturer-recommended stiffness values (Fig. 3). There were no significant interaction effects between prosthetic model, stiffness, and/or height on net CoT ( $P \geq 0.230$ ). Additionally, there was an extremely weak but significant correlation between the RSP mechanical energy return and the elicited net CoT ( $P = 0.042$ ;  $r^2 = 0.055$ ; net CoT =  $-0.660$  RSP mechanical energy return +  $4.360$ ; Fig. 5).

There were no differences between any tested biomechanical parameters from *minutes 2.0* to *3.0* compared with *minutes 3.5* to *5.0* ( $P \geq 0.430$ ). Consequently, we only report biomechanical data collected between *minutes 3.5* to *5.0* of each trial. Residual limb stiffness values ranged from 18.7 to 82.8 kN/m and averaged  $42.5 \pm 15.1$  kN/m ( $\pm$ SD; Fig. 6). There was a moderate positive association between prosthetic stiffness (in

kilonewtons per meter) and leg stiffness ( $P < 0.001$ ;  $r^2 = 0.437$ ; leg stiffness =  $0.703$  prosthetic stiffness -  $1.623$ ; Fig. 6) and a strong positive association between residual limb stiffness and leg stiffness ( $P < 0.001$ ;  $r^2 = 0.825$ ; leg stiffness =  $0.149$  residual limb stiffness +  $8.159$ ). There was a weak yet statistically significant, positive association between prosthetic stiffness (in kilonewtons per meter) and residual limb stiffness ( $P = 0.003$ ;  $r^2 = 0.115$ ; residual limb stiffness =  $2.186$  prosthetic stiffness -  $7.704$ ; Fig. 6).

Net CoT was associated with peak braking horizontal GRF, stride frequency, and leg stiffness. Independently, every  $0.1 \times$  body weight decrease in peak braking horizontal GRF was related to a 6.4% reduced net CoT (net CoT =  $2.789$  peak braking GRF +  $4.354$ ;  $P = 0.001$ ), every 0.1-Hz decrease in stride frequency was related to an 8.3% reduced net CoT (net CoT =  $0.911$  stride frequency +  $1.099$ ;  $P < 0.001$ ), and each 1 kN/m decrease in leg stiffness was associated with a 1.8% reduced net CoT (net CoT =  $0.053$  leg stiffness +  $2.991$ ;  $P = 0.009$ ). Stance average vertical GRF ( $P = 0.592$ ), peak vertical GRF ( $P = 0.723$ ), peak propulsive horizontal GRF ( $P = 0.063$ ), and ground contact time ( $P = 0.116$ ) were not associated with net CoT.

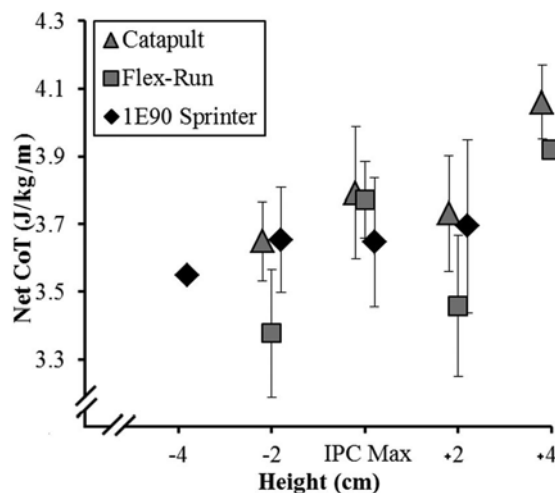


Fig. 4. Mean ( $\pm$ SE) net metabolic cost of transport (CoT) as a function of using different models of running-specific prostheses (RSPs) at different heights (in centimeters) using the stiffness category that produced the lowest net CoT. Symbols are offset for clarity. IPC Max indicates the prosthetic height for each participant that elicits the maximum competition height based on the International Paralympic Committee guidelines (37a), and deviations indicate heights of  $\pm 2$  and  $\pm 4$  cm. Triangles represent use of the C-shaped Catapult, squares represent use of the C-shaped Flex-Run, and diamonds represent use of the J-shaped 1E90 Sprinter prostheses.

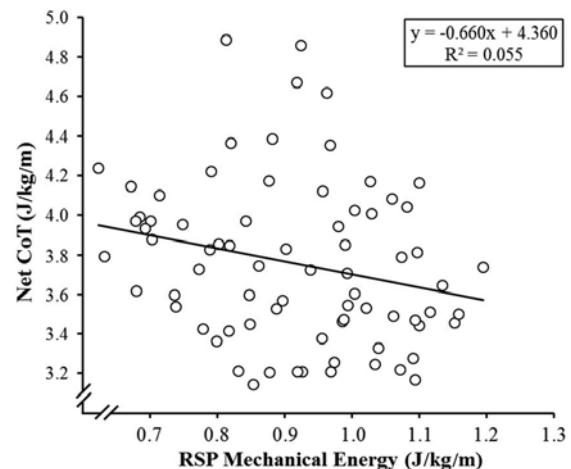


Fig. 5. The net metabolic cost of transport (CoT) as a function of running-specific prosthesis (RSP) mechanical energy return for each running trial. Increased prosthetic mechanical energy return lowered net CoT ( $P = 0.042$ ).



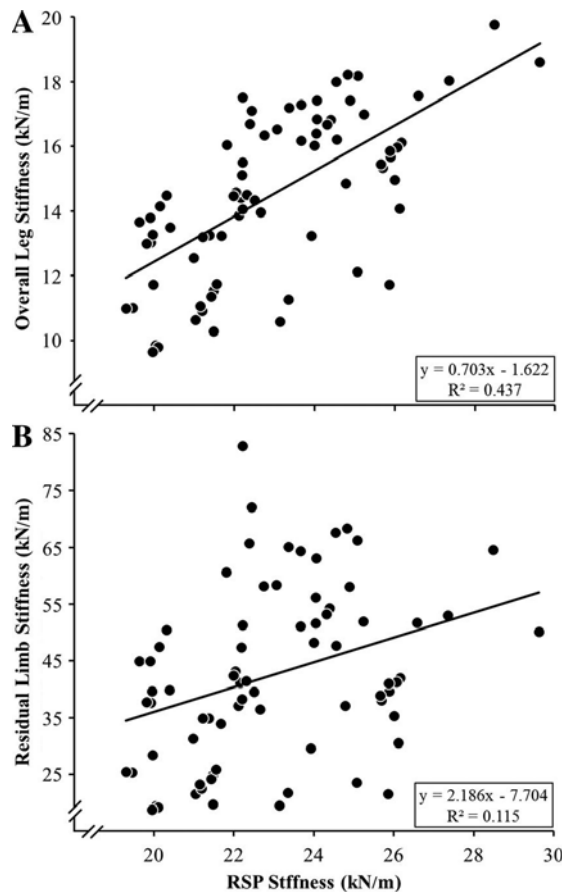


Fig. 6. Overall leg stiffness compared with running-specific prosthesis (RSP) stiffness ( $P < 0.001$ ; A) and residual limb stiffness compared with prosthetic stiffness ( $P = 0.003$ ; B). There was a positive association between both overall leg stiffness and residual limb stiffness compared with prosthetic stiffness.

## DISCUSSION

We accept our initial hypothesis based on our findings that athletes with bilateral transtibial amputations consume less metabolic energy while running with RSPs that are less stiff than manufacturer recommended. Since prosthetic stiffness category recommendations are based on user body mass, we ran a linear mixed model with prosthetic stiffness (in kilonewtons per meter) normalized to each corresponding participant's body mass. Every  $0.1 \text{ kN} \cdot \text{m}^{-1} \cdot \text{kg}^{-1}$  decrease in prosthetic stiffness (while controlling for prosthetic model) reduced net CoT by 9.2% ( $\beta = 2.499$ ;  $P = 0.012$ ), further supporting the notion that the use of less stiff RSPs reduces the metabolic cost of running for athletes with bilateral transtibial amputations. The decreased metabolic cost while using less stiff RSPs is likely related to improved biomechanics. Overall, the use of less stiff RSPs lowered peak braking GRF, stride frequency, and leg stiffness ( $P \leq 0.022$ ). Moreover, while considering prosthetic models, further linear mixed-model analyses revealed that for every 1 kN/m prosthetic stiffness reduction, net CoT decreased while using the Catapult ( $\beta = 0.085$ ;  $P < 0.001$ ) and Flex-Run ( $\beta = 0.084$ ;  $P < 0.001$ ) but not the 1E90 Sprinter ( $P = 0.258$ ) prostheses (Fig. 3). Therefore, the effects of prosthetic stiffness on net CoT depend on the prosthetic model. Future studies should investigate whether use of C-shaped RSPs that are more than one stiffness category lower

than the manufacturer recommended optimize net CoT and whether net CoT remains independent of the 1E90 Sprinter or J-shaped prosthetic stiffness across a wider range of stiffness values.

In addition to improved biomechanics, the metabolic cost of running when using the J-shaped 1E90 Sprinter prostheses compared with the C-shaped RSPs may be due to better sagittal plane alignment, reduced mechanical energy dissipation (less hysteresis), and/or enhanced stability. The sagittal plane alignment of the 1E90 Sprinter prostheses may have elicited GRF vectors that were more aligned with the stance limb, thus mitigating muscular force requirements (13, 14). Also, J-shaped RSPs return ~1% more of the stored elastic energy (~1% less hysteresis) than C-shaped RSPs (11), thus potentially minimizing mechanical work performed by the muscles when using the 1E90 Sprinter prostheses compared with the C-shaped RSPs. Another possible explanation for the reduced metabolic cost of running with the 1E90 Sprinter prostheses compared with the C-shaped RSPs may have been owed to improved lateral stability (6–9). Arellano et al. (10) found that an athlete with bilateral transtibial amputations had greater mediolateral “foot” placement variability than nonamputees while running (10), indicating that lateral balance is compromised compared with nonamputees. Accordingly, it is possible that there is a considerable metabolic cost of maintaining lateral balance during running for athletes with bilateral transtibial amputations (6–9). Overall, 1E90 Sprinter prostheses are wider (0–2.5 cm) and thicker (0.1–0.9 cm) than the C-shaped RSPs at each segment (i.e., proximal, medial, and distal; Refs. 30a, 51a, 51b). Thus the design of the 1E90 Sprinter prostheses may have improved mediolateral stability and consequently reduced the metabolic cost of running compared with the use of C-shaped RSPs.

The improved metabolic cost of running with the J-shaped 1E90 Sprinter vs. C-shaped RSPs was despite the relatively heavy attachments used for the 1E90 Sprinter prostheses. The mass of two brackets plus 1E90 Sprinter prostheses (2,008 g) were 384 and 630 g greater than the mass of the Catapult and Flex-Run prostheses, respectively. Adding mass to the lower legs or feet of nonamputees increases the metabolic cost of running, such that 100 g added to the feet increases metabolic cost by ~1% (22, 37, 45). It is likely that the use of standard, lighter attachments for the J-shaped 1E90 Sprinter prostheses would further decrease the metabolic cost of running.

Numerical reductions in three biomechanical variables, peak braking GRF, stride frequency, and leg stiffness, were associated with improved net CoT. Decreased peak braking GRFs may reduce metabolic cost by mitigating the muscular force generated by the legs during running (9, 24). The potential influence of stride frequency and leg stiffness on metabolic cost is not straightforward. The metabolic cost of running for nonamputees increases when they adopt unnatural stride frequencies (23, 35). However, in the present study, participants used a self-selected stride frequency for each prosthetic configuration. Similarly, when nonamputees adopt higher or lower leg stiffness values than preferred, their metabolic cost of running increases (23, 26, 50, 54). Hypothetically, compliant leg springs decrease the metabolic cost of running compared with stiffer leg springs by prolonging ground contact time and by storing and returning more elastic energy per unit of applied force. Longer ground contact time enables athletes to produce

the required vertical force on the ground with slower, more economical muscle fibers (41, 43, 52). Also, storing and returning more elastic energy during running mitigates the muscular mechanical work needed to sustain running, which also elicits more economical muscular force production (5, 20, 21, 55). However, the notion that force generated by isometric muscle contractions is more economical than continuous stretching-shortening contractions has been challenged. Holt et al. (36) reported that while generating force, frog muscles in vitro consume metabolic energy at the same rate when continuously stretching and shortening vs. operating isometrically. Moreover, stiffer leg springs generally have an improved effective mechanical advantage compared with compliant leg springs (13, 14) due to reduced ankle, knee, and hip joint flexion (27, 28). Because the greatest GRF magnitudes are approximately vertical and occur when the runner's center of mass is directly above the center of pressure of the body (Fig. 1; Refs. 15, 25, 47), reduced joint flexion theoretically decreases peak GRF-joint moments due to shorter moment arm lengths, mitigating muscular force requirements. Collectively, moderate leg stiffness seems to minimize the metabolic cost of running by optimizing the interplay of multiple biomechanical factors.

We accept our second (null) hypothesis; the metabolic cost of running was independent of prosthetic height. Since the influence of prosthetic height did not achieve statistical significance, our results generally support those of Williams and Cavanagh (60), who reported a weak relationship between the metabolic cost of running and the leg lengths of nonamputees. Athletes with long residual limbs that compete in sprint events within the T43 classification (athletes with bilateral below-knee amputations) may not be able to use C-shaped RSPs because their overall height would exceed the IPC's regulated competition height (37a). However, based on the disassociation between prosthetic height and net CoT from our study, these athletes could increase their height beyond the IPC's regulated competition height without affecting their distance running performance. Further linear mixed-model analyses reveal that prosthetic height was unrelated to stride frequency ( $P = 0.162$ ) or leg stiffness ( $P = 0.914$ ) but was associated with peak braking GRF ( $\beta = 0.005$ ;  $P = 0.049$ ). For every 2-cm increase in prosthetic height, peak braking GRF magnitude increased 4.8%. Additional paired two-tailed  $t$ -tests revealed that prosthetic mass was similar across height alterations ( $P \geq 0.352$ ), indicating that prosthetic mass did not statistically affect our prosthetic height results.

To our knowledge, only one study has investigated the influence of prosthetic configuration on a facet of running performance. Tominaga et al. (57) altered the sagittal plane alignment of the RSPs  $\pm 4^\circ$  for athletes with unilateral transtibial amputations and found no association between alignment and running speed during the acceleration phase of an all-out sprint (57). However, sagittal plane alignment may affect net CoT based on our previous finding that a  $1^\circ$  alignment change alters prosthetic stiffness 0.46–0.79 kN/m, depending on the prosthetic model (11).

Similar to Kerdok et al. (39), we found that reduced in-series stiffness with respect to the stance leg as well as increased mechanical energy return from the in-series spring were associated with a reduced metabolic cost of running. In contrast to Kerdok et al. (39), who found a strong correlation between the

metabolic cost of running and the mechanical energy return of the in-series compliant surface, we found an extremely weak correlation between the metabolic cost of running and the mechanical energy returned by the in-series RSPs ( $r^2 = 0.055$ ). Furthermore, we found that prosthetic mechanical energy return was independent of prosthetic stiffness (linear regression:  $P = 0.718$ ) and that overall leg stiffness decreased with reduced in-series stiffness. Collectively, it appears that athletes with and without amputations both run with lower metabolic costs when in-series stiffness is reduced, yet the underlying mechanisms responsible for these changes are different.

We found that the overall leg stiffness (residual limb plus RSP in-series stiffness) of athletes with bilateral transtibial amputations is affected by changes in prosthetic stiffness. Our results coincide with those of McGowan et al. (46), suggesting that prosthetic stiffness governs overall leg stiffness. We found a positive association between residual limb stiffness (biological limb stiffness) and prosthetic stiffness (in-series stiffness; Fig. 5). Therefore, we reject our third hypothesis. Our results are in contrast to those of nonamputee runners whom adjust their biological leg stiffness with altered in-series (surface) stiffness to maintain overall leg plus in-series stiffness (29, 30, 39). Our results indicate that in-series prosthetic stiffness affects the running mechanics of athletes with bilateral transtibial amputations; consequently, traversing terrain of varying compliance likely alters their running mechanics. Biomechanically, leg stiffness is a composite of sagittal plane joint torsional stiffness and leg segment geometries (27, 28, 48). Since RSP stiffness cannot yet be modulated neurally (11) and the hip joint has a negligible influence on leg stiffness (27, 28, 48), it is possible that athletes with bilateral transtibial amputations primarily rely on knee joint mechanics to alter leg stiffness. Future studies are needed to understand the mechanisms underlying the unique leg stiffness results of athletes with bilateral transtibial amputations.

Previously, the metabolic cost of running had only been reported for two athletes with bilateral transtibial amputations (42, 59); this data set now totals seven athletes with bilateral transtibial amputations (Table 2). Selecting the most economical trial for each of our participants and the reported values in the literature, average gross CoT ( $\text{ml O}_2\cdot\text{kg}^{-1}\cdot\text{km}^{-1}$ ) from these seven athletes with bilateral transtibial amputations is

Table 2. The lowest and highest elicited gross metabolic cost of transport (CoT) values for the participants in the present study (athletes 1–5) as well as those reported in the literature (athletes 6 and 7)

Athletes with Bilateral Transtibial Amputations	Lowest Gross CoT, $\text{ml O}_2\cdot\text{kg}^{-1}\cdot\text{km}^{-1}$	Highest Gross CoT, $\text{ml O}_2\cdot\text{kg}^{-1}\cdot\text{km}^{-1}$
1	207.0	264.0
2	185.6	216.0
3	182.0	230.2
4	174.2	204.2
5	182.4	220.7
Average $\pm$ SD	186.2 $\pm$ 12.3	227.0 $\pm$ 22.7
6	174.9	N/A
7	216.5	N/A
Average $\pm$ SD	188.9 $\pm$ 16.3	

Athlete 6 is from Weyand et al. (59), athlete 7 was tested in Brown et al. (17), and their individual CoT data were reported by Kram et al. (42). N/A, not applicable.



188.9 ± 16.3 ml O<sub>2</sub>·kg<sup>-1</sup>·km<sup>-1</sup> (mean ± SD). For context, Olympic-qualifying, subelite, and good nonamputee runners tested by Morgan et al. (49) elicited mean gross CoT values of 181.9 ± 9.1, 187.5 ± 9.7, and 190.5 ± 13.6 ml O<sub>2</sub>·kg<sup>-1</sup>·km<sup>-1</sup> (mean ± SD), respectively. Furthermore, our study demonstrates the importance of optimizing prosthetic model and stiffness recommendations since the least economical prosthetic configuration for each of our participants yielded average gross CoT values that were 21.9% higher than their most economical trials (227.0 ± 22.7 vs. 186.2 ± 12.3 ml O<sub>2</sub>·kg<sup>-1</sup>·km<sup>-1</sup>; paired 2-tailed *t*-test; *P* = 0.001; Table 2).

We were unable to match the maximum IPC competition height for all participants and prosthetic models due to residual limb lengths and/or prosthetic component dimensions. In turn, we adopted a statistical approach that accounted for the discrepancies in participant height across trials. Also, our participants used 2 sets of sockets to complete our protocol (1 set for C-shaped RSPs and 1 set for J-shaped RSPs), thus there could have been unequal residual limb movement within the different sockets. This may have led to varying levels of muscular contraction and/or mechanical energy dissipation. Unfortunately, little is known regarding how prosthetic sockets affect athletic performance. Future studies aimed to understand the influence of socket design on the performance of athletes with lower limb amputations are warranted. Furthermore, 2 of the 5 participants were unable to complete all trials at 3.0 m/s while maintaining primarily aerobic metabolism. As a consequence, those 2 participants completed their trials at 2.5 m/s; therefore, we used net CoT because of its general independence with running speed (9, 44, 49), which we confirmed with our data set using a linear mixed-model analysis (*P* = 0.572). Even though we present the largest data set of running metabolic costs and biomechanics from athletes with bilateral transtibial amputations to date, our relatively small sample size may have falsely led us to accept null hypotheses (type II error) that would be detected with a larger participant cohort.

**Conclusions.** Prosthetic model and stiffness, but not height, influence the metabolic cost of running for athletes with bilateral transtibial amputations. While controlling for prosthetic stiffness (in kilonewtons per meter), using the Flex-Run and the 1E90 Sprinter prostheses yielded lower net metabolic cost of transports compared with using the Catapult prostheses. Across prosthetic models, use of RSPs that are less stiff than manufacturer recommended (e.g., numerically lower stiffness category) reduced the metabolic cost of running. The use of RSPs of different heights spanning a 4-cm range had no effect on the metabolic cost of running. Mechanically, the leg stiffness of athletes with bilateral transtibial amputations is governed by in-series prosthetic stiffness. In all, athletes with bilateral leg amputations can minimize their metabolic cost of running through the use of RSPs that are optimally designed and have lower prosthetic stiffness compared with the manufacturer-recommended.

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#### DISCLOSURES

The authors have no conflicts of interest to disclose. All of the running-specific prostheses used in our study were donated from the respective manufacturer.

#### AUTHOR CONTRIBUTIONS

O.N.B., P.T., and A.M.G. performed experiments; O.N.B., P.T., and A.M.G. analyzed data; O.N.B., P.T., and A.M.G. interpreted results of experiments; O.N.B., P.T., and A.M.G. prepared figures; O.N.B., P.T., and A.M.G. drafted manuscript; O.N.B., P.T., and A.M.G. edited and revised manuscript; O.N.B., P.T., and A.M.G. approved final version of manuscript.

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## ★ RAISING THE BAR: EXTREMITY TRAUMA CARE ★

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## RAISING THE BAR: EXTREMITY TRAUMA CARE

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## **“Raising the Bar” in Extremity Trauma Care: A Story of Collaboration and Innovation**

*Fred A. Cecere, MD; Bill W. Oldham, MBA*

Today’s military health system is working in remarkable ways to provide complex extremity trauma care that helps injured service members reach their highest level of function. The difference in outcomes as a result is staggering. In the 1980s, only 2% of soldiers remained on active duty following limb loss, despite relatively minor injuries such as a partial hand amputation.<sup>1</sup> By 2010, 19% of service members remained on active duty after suffering limb loss caused by major extremity trauma. About 25% of this group actually returned to theater, even though their injuries were much more devastating than those suffered during previous conflicts.<sup>2</sup>

Wounded soldiers now have access to cutting-edge technologies, multidisciplinary care, and research efforts aimed at realizing optimal outcomes for a population already used to performing at high levels. The approach is holistic and family centered, focusing more on the patient’s ability than disability. Best of all, advances in the care of these patients offer benefits to other injured service members as well as the civilian population.

This work is possible because of the synergies that exist between programs operating through the Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA) across the patient care spectrum. The result is complementary rather than competing care that begins at the point of injury and continues for the rest of a patient’s life.

Efforts to cultivate this collaborative approach to orthopedic rehabilitation care have been bolstered by three separate but interconnected programs that have identified and developed critical research capabilities and infrastructures that translate research advances into clinical care for patients with traumatic extremity injuries.

The Extremity Trauma and Amputation Center of Excellence (EACE) was created by Congressional mandate as a joint enterprise between the DoD and the VA to develop a comprehensive strategy to help service members with traumatic injuries optimize their quality of life.

The Center for Rehabilitation Sciences Research (CRSR) was established to advance the rehabilitative care for service members with combat-related injuries while also educating the next generation of military medicine professionals.

The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium was developed as a research capacity building program to further establish

research infrastructures and investigators at DoD and VA sites and to launch a series of multiteam clinical research initiatives.

These programs operate independently, but they are designed to be interdisciplinary and collaborative in nature. This complementary approach is reflective of the efforts by the DoD to address the complex health needs of the combat wounded before they reach the VA, which has already had an established amputee and rehabilitation science program. Together, they provide a unique opportunity to strengthen DoD/VA research programs and influence the long-term direction of care for this unique patient population.

It is an approach that is working, as evidenced by a 2015 report by the Defense Health Board on the sustainment and advancement of amputee care.<sup>3</sup> It found that the DoD is “leading the Nation and the world in extremity trauma and amputee science and care through its infrastructure, systems and approach.” That same report also reiterated the need for collaborations between institutions, practitioners, and researchers across disciplines and organizations in order to sustain these advancements.

Whether it is team members from the EACE and the BADER Consortium embedding at military treatment facilities (MTFs) to help answer clinically relevant questions and support research in high-priority areas or CRSR staff working to define and validate rehabilitation strategies for injured service members, the focus remains constant—to help these wounded warriors get back to the life they were living before their traumatic injuries.

By working collaboratively, researchers do not have to give up their autonomy. Indeed, each domain of rehabilitation care can and should be able to work independently.

The resultant creativity and energy is evidenced by the myriad of research projects already underway at MTFs and VA centers around the country. These researchers are not constrained by working toward the same goal—helping patients regain their highest functional levels—but rather, they are empowered to meet those goals in different ways.

One project funded by the Defense Medical Research and Development Program and supported by the EACE and BADER focused on preventing falls in service members with amputations through the use of advanced rehabilitation training.<sup>4</sup> At CRSR, they are finding improvements in pain management strategies that can improve the quality of life for patients with severe combat injuries. The BADER Consortium supports the goal of optimal outcomes by providing needed administrative assistance and infrastructure support to help address important gaps in clinical orthopedic rehabilitation research and patient care.

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MTFs and VA medical centers are uniquely positioned to undertake this mission of restoring function. The networks that already exist at these facilities enable the orderly adoption of cutting-edge technological devices and associated rehabilitation techniques to enhance patient function.

These advances are being developed, tested, and evaluated by the same high-performing, motivated population most likely to benefit from them. In this capacity, the MTFs and VA medical centers can serve as the nation's premiere translational and clinical trial network for traumatic amputee rehabilitation, offering possibilities for personalized care and optimal function of these devices.

Microprocessor-controlled prosthetic knees offer tangible examples of how injured service members are getting access to cutting-edge care, but it is providing these devices with a well-designed rehabilitation program that truly offers the opportunity for patients to return to their busy lives and work, thereby making the goal of optimizing outcomes a reality. The Return-to-Run program pioneered at the Center for the Intrepid is one example of coupling high-tech with rehabilitation, resulting in long-term improvements in physical performance, pain- and patient-reported outcomes.

In the same vein, research has found that the body, mind, and spirit should be jointly considered following traumatic injuries. The Military Extremity Trauma Amputation/Limb Salvage study<sup>5</sup> showed that service members who underwent amputation rather than limb salvage returned to full activity and had a lower likelihood of post-traumatic stress disorder.

There was a time when simply helping a patient regain some aspect of mobility was considered a success. But this generation of injured service members has more demanding medical and interpersonal needs than previous cohorts. These young men and women typically lived highly active and athletic lifestyles before their injuries. They want to return to their busy lives, whether it is through the use of prosthetic and orthotic devices that help them regain their mobility or specialized rehabilitation training that helps them adapt to changing terrains.

The needs of this unique population have spurred many stunning advancements in patient care over the past 15 years. It is why programs like the EACE, CRSR, and BADER have been able to thrive in a relatively short amount of time.

Much is still not known about the challenges injured service members will face in the future. Many of these patients are young, but so are the programs providing the resources to support these critical research efforts. These heroes, who face lifelong adaptations to the rigors of the world, need continued and dedicated teams of specialists trained in their

unique challenges. As the research into these areas faces greater challenges, it is important for the centers and the collaborations to be allowed to grow and mature.

In the coming years, there needs to be an increased effort to develop research enterprises that will wield the greatest impact on current and future limb loss partners. Great research advances have been made during the recent 15 years of conflicts, but it is critical that these successes be sustained in peacetime.<sup>3</sup>

Vagaries of combat—along with the fluctuations in the number of patients with traumatic extremity injuries who require care—present funding and staffing challenges that could threaten medical advancements and treatment breakthroughs in the future. Only when clinicians and researchers work together—along with the DoD and VA leadership—to develop programs and research capabilities with the greatest potential for impacting our wounded will these challenges be overcome.

It is through this larger coordination of effort we can ensure military health professionals will continue to raise the bar in the development and implementation of a new normal where service members who have experienced all kinds of extremity trauma can achieve their highest level of function and enjoy a better quality of life.

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## The Extremity Trauma and Amputation Center of Excellence: Overview of the Research and Surveillance Division

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**ABSTRACT** Congress authorized creation of the Extremity Trauma and Amputation Center of Excellence (EACE) as part of the 2009 National Defense Authorization Act. The legislation mandated the Department of Defense (DoD) and Department of Veterans Affairs (VA) to implement a comprehensive plan and strategy for the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputation. The EACE also was tasked with conducting clinically relevant research, fostering collaborations, and building partnerships across multidisciplinary international, federal, and academic networks to optimize the quality of life of service members and veterans who have sustained extremity trauma or amputations. To fulfill the mandate to conduct research, the EACE developed a Research and Surveillance Division that complements and collaborates with outstanding DoD, VA, and academic research programs across the globe. The EACE researchers have efforts in four key research focus areas relevant to extremity trauma and amputation: (1) Novel Rehabilitation Interventions, (2) Advanced Prosthetic and Orthotic Technologies, (3) Epidemiology and Surveillance, and (4) Medical and Surgical Innovations. This overview describes the EACE efforts to innovate, discover, and translate knowledge gleaned from collaborative research partnerships into clinical practice and policy.

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### INTRODUCTION

In 2009, Congress legislated the creation of the Extremity Trauma and Amputation Center of Excellence (EACE) as a joint enterprise between the Department of Defense (DoD) and Department of Veterans Affairs (VA) to optimize the quality of life (QoL) of service members and veterans who sustain extremity trauma or amputation.<sup>1</sup> Congress directed

the EACE to implement a comprehensive plan and strategy, conduct clinically relevant research, foster collaborations, and build partnerships across multidisciplinary international, federal, and academic networks. In accordance with this mandate, the EACE's mission is focused on the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputations. The purpose of this editorial is to provide an overview of the EACE efforts to innovate, discover, and translate knowledge gleaned from collaborative research partnerships across established DoD, VA, and academic research programs.

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### BACKGROUND

At the time of the first EACE staff hire in September 2011, the U.S. military was engaged in nearly 10 years of continuous combat. As of October 1, 2015, data compiled from the Expeditionary Medical Encounter Database, Naval Health Research Center, indicate that approximately 26,000 traumatic extremity injuries resulted from deployments during Operations Enduring Freedom (OEF), Iraqi Freedom, (OIF) and New Dawn (OND). These injuries ranged in severity and complexity, with nearly 50% involving the lower limbs.<sup>2</sup> From 2001 to 2015, 1,687 individuals with major limb amputations from OIF, OEF, and OND were documented in the EACE Amputee Registry. Of these individuals, 69% suffered a single limb loss injury and 31% lost multiple limbs. The overall incidence of extremity injuries from these operations is consistent with previous wars, comprising more than half of all combat wounds.<sup>2</sup>

With extremity injuries sharply rising early in the conflicts, leadership within the DoD and VA health care systems realized the need for specialized systems of care that could deliver concentrated, interdisciplinary health care required by



individuals with severe combat-related injuries. Together, the DoD and VA launched efforts to create these systems by both building upon existing resources and acquiring new capabilities in partnerships with academic institutions, veteran service organizations, industry, and other federal agencies.

### **DoD Clinical Care**

In 2001, the U.S. Army designated Walter Reed Army Medical Center, now Walter Reed National Military Medical Center (WRNMMC), as the flagship location to provide extremity trauma and amputee care for the U.S. military. In 2003, the U.S. Army established the Armed Forces Amputee Patient Care Program to provide state-of-the-art surgical and rehabilitative care to patients with limb loss.<sup>3</sup> This program leveraged resources and subject-matter experts across the Military Health System to optimize patient outcomes. By 2007, the DoD had established three state-of-the-art Advanced Rehabilitation Centers (ARCs) to provide clinical rehabilitative care services and promote a return to high-level function: the Military Advanced Training Center (MATC) at WRNMMC, the Center for the Intrepid at San Antonio Military Medical Center (SAMMC), and the Comprehensive Combat and Complex Casualty Care (C5) Program at the Naval Medical Center San Diego. These DoD ARCs continue to deliver coordinated, patient-centered care and management through interdisciplinary teams.<sup>4</sup>

### **VA Clinical Care**

The VA health care system has well-established clinical rehabilitation programs for veterans experiencing a myriad of disabling conditions, including spinal cord injury, neurodegenerative diseases, mental health conditions, stroke, brain injury, low vision/blindness, and limb loss. While the majority of all veterans with amputation experienced new limb loss secondary to vascular disease and diabetes, the VA provides a lifelong continuum of care for patients with both disease- and trauma-related amputation.<sup>5</sup> As a result of injuries suffered during OEF/OIF/OND, there was an increase in the number of veterans with combat-related limb loss seen by the VA. Of those, 50% also sustained concomitant traumatic brain, peripheral nerve, spinal cord, soft tissue, and/or psychological injuries such as post-traumatic stress disorder.<sup>6</sup> This combination of multiple injuries resulting from the same traumatic event was termed “polytrauma” by the VA for the purpose of defining the system of care services that would be needed as combat operations continued.<sup>7</sup> Public Law 108-422, also known as the Veterans Health Programs Improvement Act of 2004, charged the VA to create “centers for research, education, and clinical activities on complex multi-trauma associated with combat injuries.”<sup>8</sup> In 2005, the Polytrauma System of Care (PSC) was established in conjunction with the designation of four Polytrauma Rehabilitation Centers (PRCs). The PSC is an integrated network of specialized rehabilitation programs dedicated to serving

veterans and service members with both combat- and civilian-related traumatic brain injury and polytrauma injuries, including limb loss.

In 2008, emulating the PSC model, the VA established an Amputation System of Care (ASoC). The ASoC is committed to delivering a full range of amputation care and rehabilitation services, including use of telehealth technologies, to more than 80,000 veterans who have sustained an amputation.<sup>9</sup> The ASoC consists of a hub-and-spoke system made up of 4 care components: 7 Regional Amputation Centers (RACs), 18 Polytrauma Amputation Network Sites (PANS), 108 Amputation Care Teams (ACTs), and Amputation Points of Contact (APoC) across the United States and Puerto Rico.<sup>5</sup>

### **DoD-VA Research Scope and Partnerships**

The need for innovative surgical and rehabilitation technologies and treatment strategies increased exponentially because of severe injuries sustained by service members throughout recent conflicts. In response to this demand, research programs within the DoD and VA redirected efforts toward caring for the combat wounded. These programs broadened their research scope to include traumatic brain injury, blast-related sensory loss, amputation, polytrauma, and the development of advanced prosthetics for combat-injured service members. These efforts were not performed in isolation—multiple partnerships and collaborations across federal agencies, academic institutions, and industry were created and/or expanded to address growing clinical needs. The DoD and VA increased collaborative efforts in many clinical research areas and coauthored a “guidebook” that provides suggestions for identifying collaborators with common research goals, summarizes administrative and funding mechanisms, and identifies procedures for establishing collaborations.<sup>10</sup>

### **DoD Research Support**

One core source of research support within the DoD is the U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP), which provides Defense Medical Research and Development Program (DMRDP) execution management support for the six Defense Health Program core research program areas (\$452.6 million fiscal year [FY] 2010–2015, estimated \$299.6 million FY 2016).<sup>11</sup> Each major research program area is guided by a Joint Program Committee (JPC) comprised of DoD and non-DoD medical and military technical experts who translate guidance into research and development needs. They also have key responsibilities for making funding recommendations and providing program management support.

The EACE research efforts are most closely aligned with Joint Program Committee-8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP), which seeks to find, evaluate, and fund cutting-edge research in reconstruction,



rehabilitation, and definitive care to improve outcomes, restore function, return to duty, and improve QoL for injured service members.<sup>12,13</sup> Currently, research sponsored by the JPC-8/CRM RP (\$180 million FY 2015) is focused on the following key areas: Neuromusculoskeletal Injury Rehabilitation, Pain Management, Regenerative Medicine, and Sensory Systems Traumatic Injury.<sup>13</sup>

JPC-8/CRM RP funding comes from Army and Defense Health Program core dollars as well as Congressional Special Interest (CSI) program monies that are appropriated by Congress and executed by the CDMRP. Three CSI-affiliated research programs closely align with the mission of the EACE and include the Orthotics and Prosthetics Outcomes Research Program (OPORP) (\$10 million FY 2016),<sup>14</sup> Peer Reviewed Orthopaedic Research Program (PRORP) (\$30 million FY 2016),<sup>15</sup> and Reconstructive Transplant Research Program (RTRP) (\$12 million FY 2016).<sup>16</sup>

### **VA Research Support**

In parallel to the DoD research programs, the VA Office of Research and Development (ORD) is an intramural, veteran-centric research program conducted throughout the VA health care system. For more than 90 years, ORD has had the mission “to discover knowledge and create innovations that advance health care for Veterans and the Nation.” In support of this mission, ORD’s Rehabilitation Research and Development (RR&D) Service supports and integrates pre-clinical, clinical, and applied rehabilitation research and seeks to translate research results into practice.

RR&D program areas most relevant to the EACE mission include regenerative medicine (\$26 million FY 2015), musculoskeletal/orthopedic rehabilitation (\$141 million FY 2015), and rehabilitation engineering prosthetics/orthotics (\$80 million FY 2015). Supported clinical and preclinical studies span research domains ranging from improvements in foundational science techniques and systems to prevention and screening, treatment, and follow-up care. These programs within DoD and VA are some of the past and current funding streams for studies worked on by the EACE researchers.

## **THE EXTREMITY TRAUMA AND AMPUTATION CENTER OF EXCELLENCE**

Over the past decade, DoD and VA realized a need to strengthen clinical and research ties between the two departments to reduce redundancy and maximize the impact of collective efforts. Pursuant to these complementary efforts, Congress directed the establishment of the EACE in 2008. Governance is jointly provided by the Army Surgeon General as the DoD lead component and the Director of the Rehabilitation and Prosthetics Service within the Veterans Health Administration’s (VHA) Office of Patient Care Services. At the time of writing, 41 EACE-funded staff members (37 DoD and 4 VA) are structured across 4 divisions of effort. These

divisions include Clinical Affairs, Clinical Informatics and Technology, Global Outreach, and Research and Surveillance (R&S; Fig. 1).

The Clinical Affairs Division provides many deliverables and functions, including continuing medical education and training, assistance with the translation of current research findings into clinical practice through clinical practice guidelines,<sup>17,18</sup> and clinical policies for DoD and VA.

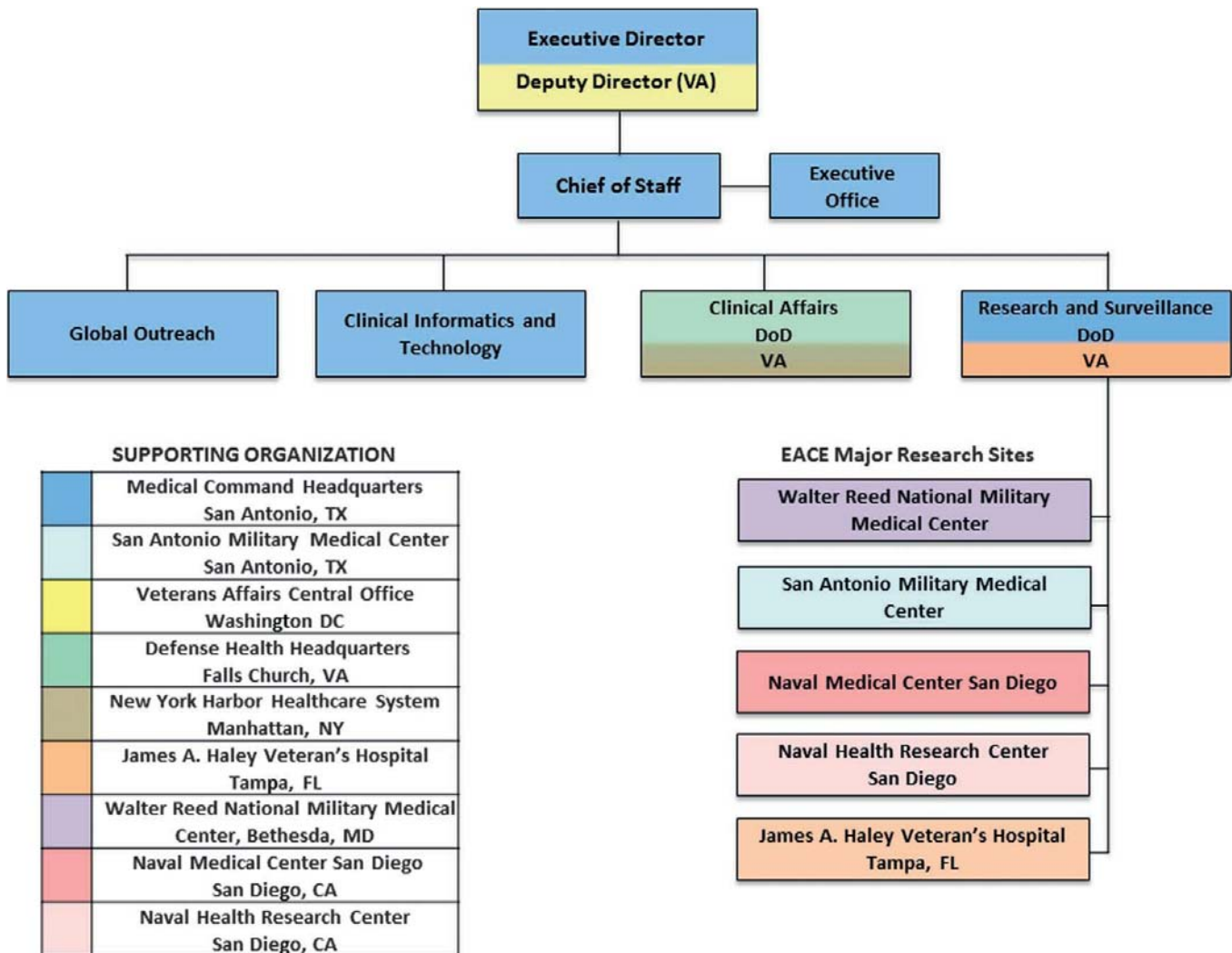
Through the Clinical Informatics and Technology Division, the EACE is developing the Defense and Veterans Extremity Trauma and Amputation Registry (DVEAR), an integrated health registry to support clinical care and research. The DVEAR will support the management of data and information reporting throughout DoD and integrate data from VA’s existing amputation repository. The DVEAR will capture and quantify key demographic, socioeconomic, and polymorbid characteristics, as well as outcomes of service members and veterans affected by traumatic extremity injury and amputation.

The Global Outreach Division strengthens international relationships through the DoD Secretarial Designation Program, which authorizes provision of amputation care for non-DoD beneficiaries. The EACE also serves as a resource for coalition nations desiring to enhance their extremity trauma and amputation care capability by providing patient consultation and developing plans for facilities and services.

### **Research and Surveillance Division**

The EACE R&S Division implemented a comprehensive plan to conduct clinically relevant research, including the hiring of clinical researchers, the establishment of collaborations and partnerships, and the identification of clinical research gaps. The EACE R&S Division consists of 26 core team members embedded at point of care within the three ARCs; the Navy Health Research Center, San Diego; and the James A. Haley Veterans’ Hospital, Tampa (Fig. 2). The EACE core and affiliated researchers (e.g., those from academic and industrial settings) work collaboratively to identify and answer clinically relevant questions through externally funded research projects (Fig. 3). Together, they have been successful in receiving support from aforementioned research programs like CDMRP, JPC-8/CRM RP, and RR&D. In addition, the EACE core and affiliated researchers have conducted research projects with support from the National Institutes of Health, the Office of Naval Research, the U.S. Navy Bureau of Medicine and Surgery, the Center for Rehabilitation Sciences Research, and the Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium.

The EACE R&S Division embraces an evidence-based framework for clinical decision-making<sup>19,20</sup> by gathering information from clinicians, patients, and research literature to identify high-priority areas for investigation. An initial clinical needs assessment conducted in 2012 by the EACE leadership identified four key research focus areas for investigations relevant to extremity trauma and amputation: (1) Novel



**FIGURE 1.** EACE organization chart showing the four divisions, research sites, and supporting organizations.

Rehabilitation Interventions, (2) Advanced Prosthetic and Orthotic Technologies, (3) Epidemiology and Surveillance, and (4) Medical and Surgical Innovations.

### **Novel Rehabilitation Interventions**

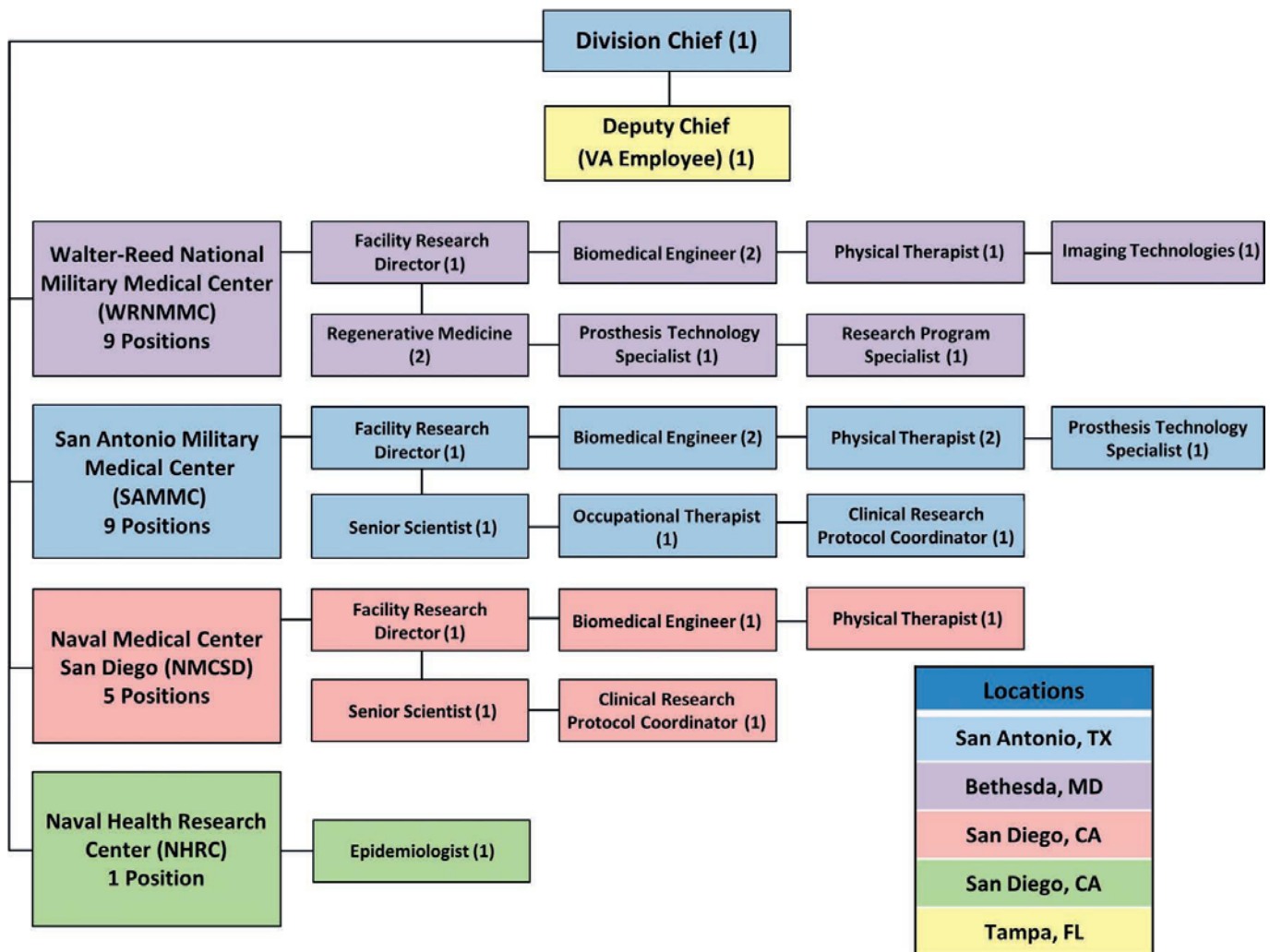
The EACE researchers are executing studies aimed at developing and determining the most efficacious treatment interventions for optimizing an individual's level of function and reintegration back to military and/or civilian communities while mitigating comorbidities and secondary health effects. These interventions are specific to impairments, functional limitations, activity restrictions, and assistive devices.

One such EACE-supported intervention focuses on preventing falls in service members with transtibial amputations through advanced rehabilitation training using a microprocessor-controlled treadmill.<sup>21</sup> The study demonstrated a significant improvement in stumbles and falls. After receiving the advanced rehabilitation training, 60% of the subjects ( $N = 11$ ) reported a decrease in stumbles and falls, and all subjects

reported that their uncontrolled falls had decreased to zero. This reduction of stumbles and falls was maintained over the 6-month follow-up period.

The EACE researchers have also used high-end virtual reality environments (Computer Assisted Rehabilitation ENvironment, Motekforce Link) to develop task-specific assessments and treatment interventions related to participation in military and civilian activities. Assessment applications were created to quantify function and identify deficits related to walking stability and mechanics during perturbations,<sup>22,23</sup> cognitive tasks,<sup>24</sup> and/or military-specific tasks.<sup>24</sup> Investigational treatment interventions within the virtual reality environments include utilization of direct and indirect visual feedback during gait, visual-vestibular habituation techniques,<sup>24</sup> and military task-specific rehabilitation.

The EACE researchers are collaborating with industry and academic partners to leverage motion-tracking game technology to extend virtual reality therapy into patients' homes through interactive and entertaining game experiences. Finally, while



**FIGURE 2.** EACE Research and Surveillance Division's research personnel positions at DoD and VA sites.

many inventions focus on functional limitations and participation restrictions, new studies are looking at strategies such as blood-flow restriction resistance training to increase muscular strength. Through this form of training, individuals may be able to experience muscular strength and hypertrophic gains at a lower resistance than conventionally employed.<sup>25</sup> The EACE researchers are investigating whether lower resistance with blood-flow restriction should reduce the pain associated with rehabilitation, increase patient compliance, and result in greater strength gains at discharge. Preliminary results in the lower extremities are promising and clinical trials for individuals with upper limb injuries are planned.

### **Advanced Prosthetic and Orthotic Technologies**

Following the physical or functional loss of their limb(s), service members and veterans are often reliant on prosthetic and orthotic devices to return to activities of daily living, recreation, and occupation. Throughout the recent conflicts,

advances in technology have led to the availability of novel devices such as improved microprocessor-controlled prostheses, active power-producing prostheses, myoelectric-controlled prostheses, and exoskeletal orthoses. The functional demand and complexity of these systems necessitated studies to examine the efficacy of advanced prosthetic and orthotic devices, specifically ease of fitting and operation, improved safety and/or function, and optimal prescription parameters to meet specific patient needs. The EACE researchers leveraged advanced assessment tools within the three ARCs and the James A. Haley Veterans' Hospital to amass nearly a decade worth of data from patients who use advanced prosthetic and orthotic devices.

These efforts have contributed to a global medical body of knowledge on emerging and maturing prosthetic technologies, such as myoelectric upper-limb prostheses,<sup>26,27</sup> microprocessor-controlled prosthetic knees,<sup>28–31</sup> powered prosthetic knees,<sup>31</sup> and powered prosthetic ankle-foot systems.<sup>32–34</sup> The underlying intent of these investigations was to determine if the technologies provide benefit to patient function across a





**FIGURE 3.** EACE research sites and collaborators across the United States. Not shown are academic and industry research partners in Austria, Canada, England, Germany, and New Zealand.

variety of activities including level-ground gait,<sup>35</sup> slope<sup>36–40</sup> and stair ambulation,<sup>28,38,41–44</sup> walking during destabilizing conditions,<sup>22,23,45–48</sup> transitions from standing,<sup>31</sup> and common activities of daily living.<sup>26</sup> Since many service members with amputation are young and fit at the time of injury, the EACE researchers have re-examined factors that may influence function later in life, such as metabolic costs<sup>49–52</sup> and stability<sup>21,22,30,45,46,48,53,54</sup> during gait. Previous literature often describes older groups of dysvascular amputees. However, this cohort does not offer adequate comparisons for young, blast-related traumatic amputees. Studies conducted with this younger population of amputees provide reference data and begin to establish the prevalence and predictive factors that may lead to the onset of secondary health conditions later in life, like low back pain,<sup>55,56</sup> cardiovascular disease,<sup>57</sup> and osteoarthritis.<sup>58</sup> For example, factors such as asymmetric limb loading<sup>35</sup> and short residual limb lengths<sup>49</sup> may impact long-term outcomes and the prescription of prosthetic devices.

New orthotic technologies also continue to emerge. The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a carbon fiber ankle-foot orthosis developed at the Center for the Intrepid. It is designed to support ankle and foot structures in a posture that minimizes pain while also storing energy before releasing it at push off. It is prescribed to those with functional limb loss following severe injury to muscle, nerve, or bone.<sup>59</sup> Through collaborative efforts in research and education, this orthosis is now available for service members, veterans, and the private sector. Current and future research efforts with the IDEO focus on determining optimal device properties<sup>60–63</sup> and evaluating patient function during both recreational and military-specific activities.<sup>64,65</sup>

### Epidemiology and Surveillance

Researchers in the Epidemiology and Surveillance research focus area track service members and veterans with severe limb trauma and amputation to evaluate the effectiveness of treatment inventions and to monitor subsequent short- and long-term health and QoL outcomes. This initiative is imperative to thoroughly characterize patients and their responses to care and also to identify predictors of optimal rehabilitation outcomes. Descriptive characteristics, prevalence, and incidence of short- and long-term secondary conditions, health care utilization, QoL, and the resulting economic impact are all quantifiable factors that EACE stakeholders may use to guide health care policy and direct resources to facilitate optimal outcomes. While providing a continuously evolving view of the extremity trauma and amputation population, research in the Epidemiology and Surveillance research focus area informs, supports, and unifies efforts throughout the R&S Division lines of research.

The need for comprehensive outcome measures that can assess high-level mobility and agility has encouraged collaboration between DoD and VA to develop the Comprehensive High-Level Activity Mobility Predictor (CHAMP).<sup>66</sup> The CHAMP was assessed for reliability and validity<sup>66,67</sup> and recommendations for its clinical application disseminated through published manuscripts<sup>68,69</sup> and training seminars for DoD and VA clinicians. Reference standards from uninjured male service members along with those who sustained limb loss are provided for both the CHAMP and the 6-minute walk test to establish a guideline for goal setting and expectations.<sup>66,70</sup> The CHAMP is one example of an outcome measure that can be used to longitudinally characterize the function of male

service members as they age. The EACE researchers are continuing to develop and validate the CHAMP for female service members as well as other novel outcome measures that will improve the health of injured service members and veterans.

The EACE researchers are currently focused on conducting epidemiologic studies to evaluate the morbidity and mortality rates of two core patient cohorts with the long-term goal of maximizing their health and QoL outcomes. Specifically, individuals with severe extremity injuries have been stratified into those with (1) “acutely threatened limbs” that required immediate consideration for amputation and (2) “functionally impaired limbs” that do not require immediate consideration for amputation but cause significant limitations. The EACE researchers use local clinical data records, Defense Manpower Data Center records, the Expeditionary Medical Encounter Database (EMED), the Medical Health System Data Repository, the VA Corporate Data Warehouse, and multiple other data sources to conduct research. Central to the EACE epidemiological efforts is the ability to access the EMED, a gold standard repository of high-quality, verified, and validated combat casualty data spanning the spectrum of care and rehabilitation.<sup>71,72</sup> Within the EMED, each casualty injury record is coded by in-house Naval Health Research Center clinical staff on diagnoses (International Classification of Diseases-9/10 codes) and on injury severity, using both the Abbreviated Injury Scale and Abbreviated Injury Scale-2005 Military. Coded injury data are then mapped to tactical data describing the characteristics of the casualty event, descriptions of treatments administered within the chain of evacuation, predeployment- and postdeployment- related health information, personnel data with career and dependent history data, and finally, with longitudinal, prospective QoL outcome data.

In addition to performing retrospective epidemiologic studies, the EACE researchers have begun prospective longitudinal efforts to examine rehabilitative and QoL outcomes. Another key facet to the EACE R&S directorate is the Wounded Warrior Recovery Project (WWRP). The WWRP is a 16-year, longitudinal, prospective, informed-consent study being conducted through Naval Health Research Center, which tracks long-term QoL, mental health outcomes, pain experiences, social support, and prosthetic/orthotic use and satisfaction.<sup>73</sup> Funding for the WWRP is through U.S. Navy Bureau of Medicine and Surgery.

Complementary to the WWRP, additional surveillance studies are aimed at understanding the prevalence and prevention of developing secondary health conditions following severe extremity trauma, such as osteoarthritis, obesity, cardiovascular disease, and low back pain. These secondary conditions may exacerbate an existing disability caused by the initial extremity injury.<sup>74,75</sup> Among these secondary conditions, delayed amputations receive particular attention as individuals may eventually choose or require an elective amputation to recover function. Delayed amputations, occurring more than 90 days after initial injury, account for 10 to 15% of all combat-related amputations<sup>76</sup> and correlate with

adverse physical and psychological diagnoses.<sup>72</sup> Future studies will work to identify early predictors of delayed amputations including the specific injury, wound complications, and rehabilitation therapies that may increase or decrease the likelihood of amputation.

Findings from the EACE Epidemiology and Surveillance research focus area support EACE-specific needs related to rehabilitating and reintegrating injured service members and veterans. This research will help inform DoD and VA clinical practice recommendations, guidelines, and policy on extremity trauma and amputation care.

### **Medical and Surgical Innovations**

In recent years, significant efforts have been devoted toward developing advanced medical therapies and surgical techniques to improve the restoration of tissue form and function following traumatic composite tissue injury. The EACE, collaborating with ongoing research efforts at WRNMMC and the Uniformed Services University of the Health Sciences, is in the early stages of building a capability to conduct pre-clinical and clinical research in the broad area of medical and surgical innovations. The overarching goal of the EACE Medical and Surgical Innovations research focus area is to foster the development of next-generation regenerative medicine therapeutics and innovative surgical approaches and to accelerate the translation of the best-performing technologies to the clinic.

Regenerative Medicine (RM) focuses on replacing or regenerating human cells, tissues, or organs to restore or establish normal form and function.<sup>77</sup> Next-generation regenerative medicine therapeutics focused on restoring tissues of the extremities (i.e., muscle, bone, tendon, ligament, nerve) are particularly relevant for service members and veterans with extremity trauma and/or amputation. Additionally, many of these therapeutics that have been developed and/or investigated were supported, at least in part, by DoD and/or VA, such as the Armed Forces Institute of Regenerative Medicine. Examples of topics currently under investigation by the EACE researchers include the clinical evaluation of a biologic scaffold material to aid in the restoration of tissue structure and function following volumetric muscle loss; the preclinical evaluation of the mechanisms that drive biomaterial mediated tissue regeneration as a means to facilitate rational design of next-generation RM materials and therapeutics; the development of 3-dimensional bio-printing; and whole organ engineering capabilities, among others.

Several innovative surgical approaches have been developed to facilitate tissue reconstruction and improve limb function for individuals with traumatic extremity injuries. Examples include targeted muscle reinnervation<sup>78</sup> for prosthetic control and osseointegration, in which a prosthesis is attached directly to the skeleton of a patient with an amputation.<sup>79</sup> The EACE researchers are currently participating in several osseointegration studies, led by clinicians at WRNMMC,

whose ultimate goal is to improve the QoL for individuals with limb loss, especially those who cannot tolerate conventional, socket-based prostheses.

These RM therapeutics and innovative surgical approaches offer immense potential to promote tissue restoration, improved function, and/or enhanced QoL; however, they vary in their stage of development, with relatively few technologies having reached commercialization and/or widespread clinical implementation. Thus, continued investment by the DoD in future research and development activities is needed to realize true clinical success in re-establishing optimal function and QoL for service members and veterans with severe extremity trauma injuries. These future directions should encompass activities that span the full spectrum of the research continuum—from basic science to preclinical animal models to human clinical trials conducted by teams of clinicians and researchers from multidisciplinary fields including orthopedic surgery, regenerative medicine, bioengineering, and rehabilitation.

## CONCLUSION

Military medical research often paves the way for changes in civilian and global clinical practice, partly because of the nature of high-impact innovations and discoveries. At the time of establishment, the EACE entered richly developed clinical and research environments comprised of federal, academic, clinical, and industry leaders. Through its R&S Division, the EACE is able to leverage and expand upon existing research efforts, funding, and infrastructure to establish research in four key focus areas. Together with their collaborators and partners, the R&S Division strives to conduct research that influences clinical practice guidelines throughout the Military Health System, VA, and civilian health care networks. The EACE researchers actively compete for intramural and extramural research funding to execute scientific investigations that improve the clinical outcomes of our injured service members and veterans as they return to the highest-possible level of physical, psychological, and emotional function. The EACE R&S Division will continue to conduct relevant research and translate findings into clinical practice to improve QoL for service members and veterans. The EACE will continue to innovate and discover so that our nation's service members and veterans are provided the highest level of care.

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# The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium: Reaching in Partnership for Optimal Orthopaedic Rehabilitation Outcomes

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**ABSTRACT** The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium began in September 2011 as a cooperative agreement with the Department of Defense (DoD) Congressionally Directed Medical Research Programs Peer Reviewed Orthopaedic Research Program. A partnership was formed with DoD Military Treatment Facilities (MTFs), U.S. Department of Veterans Affairs (VA) Centers, the National Institutes of Health (NIH), academia, and industry to rapidly conduct innovative, high-impact, and sustainable clinically relevant research. The BADER Consortium has a unique research capacity-building focus that creates infrastructures and strategically connects and supports research teams to conduct multiteam research initiatives primarily led by MTF and VA investigators.

BADER relies on strong partnerships with these agencies to strengthen and support orthopaedic rehabilitation research. Its focus is on the rapid forming and execution of projects focused on obtaining optimal functional outcomes for patients with limb loss and limb injuries. The Consortium is based on an NIH research capacity-building model that comprises essential research support components that are anchored by a set of BADER-funded and initiative-launching studies. Through a partnership with the DoD/VA Extremity Trauma and Amputation Center of Excellence, the BADER Consortium's research initiative-launching program has directly supported the identification and establishment of eight BADER-funded clinical studies. BADER's Clinical Research Core (CRC) staff, who are embedded within each of the MTFs, have supported an additional 37 non-BADER Consortium-funded projects. Additional key research support infrastructures that expedite the process for conducting multisite clinical trials include an omnibus Cooperative Research and Development Agreement and the NIH Clinical Trials Database. A 2015 Defense Health Board report highlighted the Consortium's vital role, stating the research capabilities of the DoD Advanced Rehabilitation Centers are significantly enhanced and facilitated by the BADER Consortium.

## INTRODUCTION

The significant traumatic injuries to limbs sustained by service members during combat deployments in Operations Enduring Freedom, Iraqi Freedom, and New Dawn posed new chal-

lenges to Department of Defense (DoD) Military Treatment Facilities (MTFs) and U.S. Department of Veterans Affairs (VA) sites.<sup>1</sup> During active periods of conflict, the number and complexity of injuries resulting in limb loss and limb salvage grew substantially relative to past conflicts.<sup>2</sup> This is attributed to advancements in the effectiveness of body armor, rapid evacuation, and early medical attention programs.<sup>3</sup>

To address the new clinical challenges associated with combat-related limb injuries and loss, DoD and VA officials established specialized clinical programs for extremity trauma care and research, technology development initiatives in orthotics and prosthetics, and the development of consortia to conduct and support clinically focused research programs related to orthopaedics and rehabilitation.

The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium, started in September 2011, is part of that collaborative effort. Its overall goal is to strengthen evidence-based orthopaedic rehabilitation care to achieve optimal functional outcomes for wounded warriors and civilians with traumatic limb loss and limb differences.

The purpose of this article is three-fold. First, we highlight the BADER Consortium's model system and methods for supporting the establishment of impactful and sustainable research capabilities. This includes research capacity-building components, research support infrastructures, and initiative-launching studies. Second, we demonstrate results indicating

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the effectiveness of BADER Consortium activities. Finally, we present a discussion containing insights gained to date.

### **Orthopaedic Rehabilitation Research Efforts**

A review of related research programs is needed to provide context for best understanding the BADER Consortium's central role in developing these critical research infrastructures. In 2001, following an assessment of the Army Medical Department's ability to care for large populations of combat amputees, Walter Reed Army Medical Center, now Walter Reed National Military Medical Center, was established as the first specialized amputee care center.

In 2007, three DoD Advanced Rehabilitation Centers (ARCs) were established for military amputees with specialized clinical programs in orthopaedics and orthopaedic rehabilitation. These centers are the Military Advanced Training Center at Walter Reed National Military Medical Center; the Center for the Intrepid and the San Antonio Military Medical Center at the Brook Army Medical Center; and the Comprehensive Combat and Complex Casualty Care (C5) Program at Naval Medical Center San Diego. In concert with DoD efforts, the VA established an Amputee System of Care across the United States with regional amputation centers and polytrauma amputation network sites.<sup>1,4</sup>

The ARCs implemented advanced motivational and therapeutic rehabilitation care models that utilized intensive rehabilitation, peer dynamics, and advanced rehabilitation technologies with the goal of obtaining unprecedented outcomes and quality of life (QoL) following rehabilitation. As a result, service members with salvaged and amputated limbs began returning to active duty, including redeployment to combat zones.<sup>5</sup>

Efforts of the ARCs to obtain high functional and QoL outcomes have led to a series of orthopaedic technology development initiatives. The Telemedicine and Advanced Technology Research Center, a component of the U.S. Army Medical Research and Materiel Command (USAMRMC), expanded their Advanced Prosthetics and Neural Engineering Program to include a Lower Extremity Gait Systems-integrated research team. In addition, the Defense Advanced Research Projects Agency (DARPA) established the Revolutionizing Prosthetics Program in 2006. The Revolutionizing Prosthetics Program developed "two anthropomorphic advanced modular prototype prosthetic arm systems, including sockets, which offer increased range of motion, dexterity and control options."<sup>6</sup>

Stemming from a joint agreement involving multiple government agencies, the Armed Forces Institute of Regenerative Medicine (AFIRM) was launched in 2007 to accelerate research and the delivery of regenerative medicine therapies to treat the most severely injured service members. The primary focus of AFIRM research has been seeking fundamental breakthroughs in basic scientific domains at the cellular and tissue levels.<sup>7</sup>

As a natural extension of the AFIRM Consortium, the Major Extremity Trauma Research Consortium (METRC) was established in September 2009. METRC consists of a national

network of clinical centers and one data-coordinating center that work together with the DoD to conduct multicenter clinical research studies relevant to the treatment and outcomes of orthopaedic trauma sustained in the military. The overall goal of the METRC is to "produce the evidence needed to establish treatment guidelines for the optimal care of the wounded warrior and ultimately improve the clinical, functional, and QoL outcomes of both service members and civilians who sustain high-energy trauma to their extremities."<sup>8</sup>

Also in 2009, the Extremity Trauma and Amputation Center of Excellence (EACE) was legislated by Congress as a collaborative organization to enhance research partnerships between the DoD, VA, academia, and industry. One unique aspect of the EACE is a congressional mandate to "conduct research to develop scientific information aimed at saving injured extremities, avoiding amputations, and preserving and restoring the function of injured extremities."<sup>4</sup> The primary mission of the EACE is to coordinate multidisciplinary teams to conduct scientific research at the ARCs and VA sites that improves clinical outcomes and returns patients to the highest possible level of physical, psychological, and emotional functions. The scope of the EACE mission includes treatment, research, education and training, and mitigation following traumatic extremity injury and/or amputation.<sup>4</sup>

With the burgeoning increase in clinical research and advanced patient care activities, the need soon became apparent for specialized "infrastructures" that would enhance the capacity to conduct and sustain world-class orthopaedic rehabilitation research. In 2010, the DoD Congressionally Directed Medical Research Programs (CDMRP) Peer Reviewed Orthopaedic Research Program established the Orthopaedic Rehabilitation Clinical Consortium Award (ORCCA). The goal of the ORCCA was to "establish a strong infrastructure for continuing clinical studies on combat-relevant musculoskeletal injuries and products that result in changes to, or validation of, current clinical practices that lead to better outcomes for our injured warriors."<sup>9</sup>

Following that, the Center for Rehabilitation Sciences Research (CRSR) was established in 2011 to advance the rehabilitative care for service members with combat-related injuries through synergistic research projects that promote successful return to duty and community reintegration. Housed in the Uniformed Services University of the Health Sciences, CRSR is an academic arm of rehabilitation activities within the DoD and well positioned to expedite the translation of advancements into patient care settings via the education and training of future health care providers within the military healthcare system.<sup>10</sup>

### **The BADER Consortium**

In September 2011, the BADER Consortium, based at the University of Delaware (UD), received the ORCCA award.<sup>11</sup> A partnership was formed with four MTFs (the three ARCs and the Naval Medical Center Portsmouth), the EACE, VA Centers, the National Institutes of Health (NIH), academia,

and industry to rapidly conduct innovative, high-impact, clinically relevant orthopaedic rehabilitation research. Using an NIH capacity-building model approach that provides essential infrastructures and project funding to conduct impactful research, the BADER Consortium has further strengthened MTF/VA efforts to establish and support a growing orthopaedic rehabilitation research culture.

The mission of the BADER Consortium is to help establish sustainable world-class programs in orthopaedic rehabilitation research at MTFs and VA sites that result in evidence-based orthopaedic rehabilitation care. Our vision is for wounded warriors and civilians with limb loss and limb difference to routinely benefit from significant orthopaedic rehabilitation advancements, and as a result obtain optimal functional clinical outcomes and fully re-engage in life and work activities.

These goals are being realized through three primary objectives:

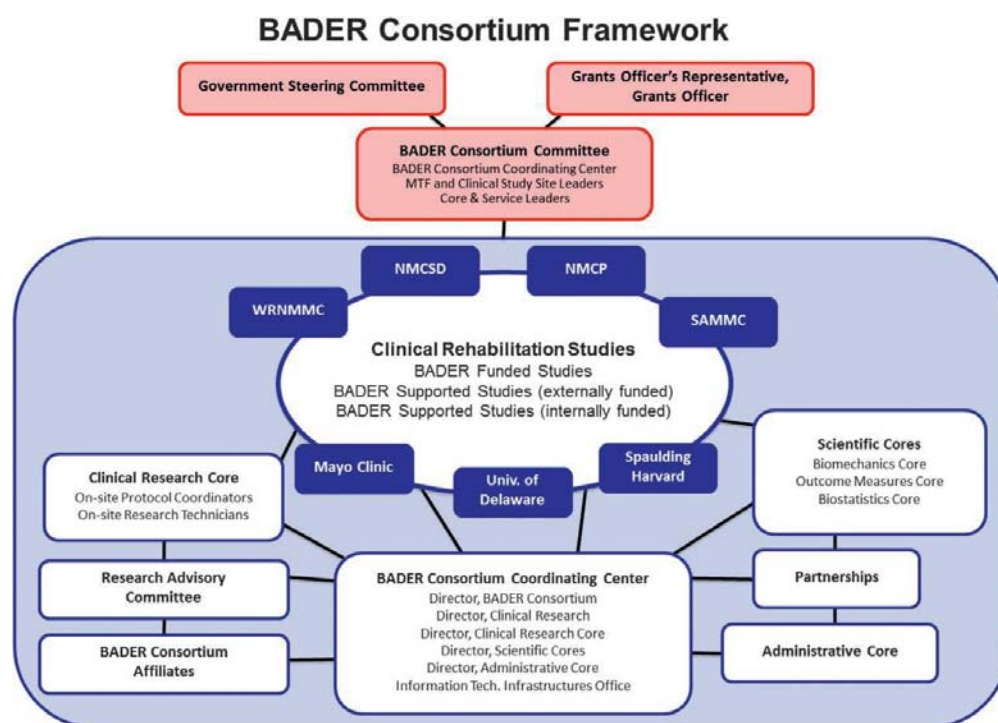
- (1) Establish infrastructures to support the advancement of orthopaedic rehabilitation research capabilities at ARCs and VA sites that promote optimal functional outcomes and QoL;
- (2) Conduct a variety of innovative, high-impact, and clinically relevant BADER-funded initiative-launching studies that lead to sustainable externally funded research programs; and
- (3) Preserve advancements in orthopaedic rehabilitation research by establishing an externally funded, self-sustaining clinical research enterprise.

## METHODS

The BADER Consortium framework (Fig. 1) is modeled on the Institutional Development Award (IDeA) Network of Biomedical Research Excellence (INBRE) program—a component of the research capacity-building IDeA program of the NIH.<sup>12</sup> Established in 1993 by congressional mandate, the IDeA program aims to increase research competitiveness and sustinment of select states. This is accomplished through support for two major programs: Centers of Biomedical Research Excellence and INBREs. The INBRE program creates infrastructure to administratively support a broad research network—typically multiple disparate research, academic, and patient care centers geographically dispersed across a state or region. The activities conducted by an INBRE Program—while broad in nature and containing policies and procedures to ensure full compliance with human subject protection, scientific integrity, and administrative federal regulations—generally reside in three categories: research capacity-building, research-support, and INBRE-funded studies for launching scientific careers in research focus areas. The BADER Consortium used this unique model to enhance the capacity at MTFs and VA sites, making it possible for more innovative, high-impact research to be conducted.

### Research Capacity-Building Infrastructures

General principles of the INBRE Program were implemented by the BADER Consortium to construct a broad, nationwide orthopaedic rehabilitation clinical research network across



**FIGURE 1.** BADER Consortium Framework as indicated by the light blue region with coordination and oversight components above.



government, academic, and industrial partners. The Consortium's research capacity-building components consist of three Scientific and Technical Cores; a Clinical Research Core (CRC); a Research Advisory Committee (RAC)—groups of scientific experts providing research reviews, advice, and expertise; and access to graduate training in Biomechanics and Movement Science.

Three Scientific and Technical Cores provide strategic support to orthopaedic rehabilitation scientists and partnering clinicians at the MTFs and VA sites. The Biomechanics Core provides the Consortium expertise and support in biomechanics and human movement analysis methodologies. The services of the Core include assistance with solving on-site problems with hardware and software, expert advice for research proposals and the development of new strategies and methods in support of clinical research areas. The Biostatistics Core at Christiana Care Health System provides episodic biostatistics support under a fee-for-service mechanism—where BADER pays the costs of incurred fees in order to be cost-effective. The Core provides pre- and postaward support to BADER-supported investigators, including but not limited to power analysis, statistical modeling, and specialized data analyses. Located at UD, the Rehabilitation Outcomes Measurement Core works directly with Principal Investigators to ensure that adequate outcomes measurement techniques are introduced and followed in the research process. The specific aim of the Rehabilitation Outcomes Measurement Core is to assist investigators in the selection, use, implementation, analysis, and interpretation of relevant outcomes variables for studies that are proposed and implemented within the BADER Consortium.

The CRC provides on-site staffing support necessary to develop, conduct, and monitor clinical studies under the direction of MTF administrative directors and clinical research leaders in support of MTF, the EACE, and/or CRSR scientific staff. The CRC is central, offering “boots on the ground” support staff to assist with research efforts at MTFs and VA sites. It is the Consortium's central body of study execution and provides MTF-led research teams with resources to develop, conduct, and monitor clinical studies, as well as day-to-day support, education, and training. Two full-time, on-site CRC staff members are dedicated to each of the MTFs. The highly skilled individuals provide MTF staff with on-site technical assistance, protocol management, and human subject recruitment support. The CRC research support infrastructures are further organized to develop and support a research-intensive culture by assisting MTF investigators with establishing a uniform and sustainable research capability that facilitates ongoing and new clinical research protocols across all participating study sites.

Research expertise and mentorship are provided through the RAC, comprising experts specializing in DoD research and priority clinical gap areas. The overall purpose of the RAC is to assure the quality and impact of BADER Consortium research. The team conducts scientific reviews of proposed projects and performs reviews of research project

progress reports. Efforts of the RAC are bolstered by an extensive group of BADER Consortium affiliates from which MTF and VA research partnerships are formed.

Access to a graduate training program in Biomechanics and Movement Science has been made available to MTF and VA center staff. Under an agreement with the College of Health Sciences at UD, the BADER Consortium provides graduate stipends for select MTF and VA research staff to enhance their skills and research expertise through the pursuit of graduate education degrees.

### **Research Support Infrastructures**

The Consortium's research support components are designed to ease the burden of administrative overhead, ensure data safety, and facilitate the forming of research partnerships. They consist of a single, Consortium-wide master Cooperative Research and Development Agreement (Consortium CRADA), a centralized protocol and data management system (PDMS), and administrative support for forming and sustaining DoD and VA research partnerships with academia and industry.

To accelerate the establishment of clinical research projects and research partnerships, BADER Consortium leadership worked with the Medical Research Law Office of the Staff Judge Advocate, USAMRMC to develop the BADER Consortium CRADA. The goal of this initiative was to jettison the traditional project-specific CRADA format—where CRADAs are customized to each project—in favor of a single consortium CRADA model that outlined the breadth of policies and procedures encountered by the activities of a national consortium.

To establish the Consortium CRADA, a selection of CRADAs from the Navy, Army, and the NIH were gathered. The content of each example CRADA was reviewed and categorized. Like categories were then combined and systematically reduced to generalized guidelines in each CRADA activity category. Each category was then tested against applicable federal regulations and active policies. The resulting “master” Consortium CRADA was virtually exercised using an array of Consortium-related scenarios. The resulting policy and implementation procedures, such as on-boarding projects and the declaration and approval of amendments, were developed. Before full implementation, the Consortium CRADA was trialed at two government sites.

Implemented via a collaborative agreement with the NIH Eunice Kennedy Shriver National Institute for Child Health and Human Development, the NIH's Clinical Trials Database serves as a rehabilitation outcomes data collection tool with patient self-report and a secure centralized web-based portal for the management of clinical study data and tissue repository information. This PDMS is a Federal Information Security Management Act-compliant tool that simplifies data sharing among member sites by standardizing research methods while simultaneously facilitating protocol tracking and compliance monitoring. While fully customizable, it uses standardized forms, common data elements, and a common vocabulary.

The centralized administrative core provides valuable support for the establishment and sustainment of research partnerships. This includes support for grand rounds presentations, site visits by potential collaborators, and scientific planning meetings at MTF and VA sites.

### Initiative-Launching Studies

The initiative-launching component contains a set of BADER Consortium-funded clinical research studies aimed at launching impactful clinical research initiatives in partnership with the MTFs and VA sites. BADER-funded projects are awarded via a peer-reviewed, limited competition award program open to the BADER Consortium Affiliates responding to a Consortium-generated call for proposals. The proposals are scientifically reviewed by the BADER RAC and ultimately selected by the Consortium's Government Steering Committee. The goal of these initiative-launching projects is to establish sustainable multiteam system partnerships and generate clinically focused results that advance patient care paradigms in critical patient care gap areas. Furthermore, this BADER-supported program is designed to provide necessary funding to propel new and early-career scientists into independent researchers leading sustainable research programs at MTF and VA sites. This funding mechanism is also ideally suited for establishing a technology translation pipeline, based on a multiteam system model, by taking emerging technologies from Telemedicine and Advanced Technology Research Center and DARPA programs and rapidly transitioning the technology across research activity category teams into clinical trials and patient care paradigms (Fig. 2).

## RESULTS

The BADER Consortium became operational in 2013 following an initial 12-month "discovery" phase. During that phase, a total of eight CRC on-site research support staff were identified in collaboration with MTF staff, hired by UD, trained and on-boarded at the MTFs. Development and testing of the

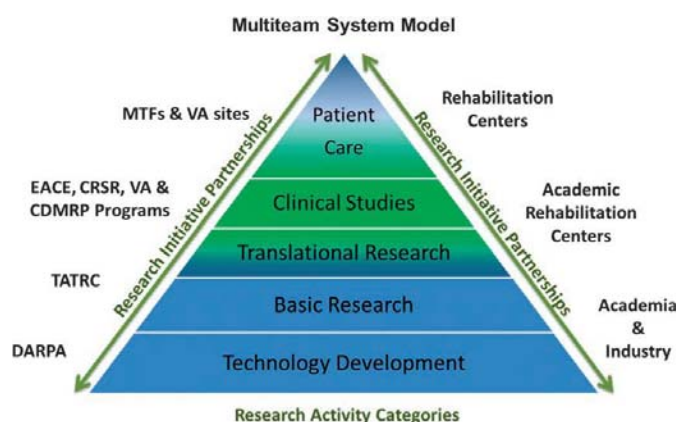
Consortium CRADA was completed on September 19, 2012. Within four months of its implementation, six partner institutions completed on-boarding to the Consortium CRADA. At the time of this report, the BADER Consortium contains nine industrial partners, eight government sites, 21 BADER-supported employees (10 are stationed full time at MTF sites), and 99 BADER-affiliated experts located at academic research sites across North America. Recently, a generic version of the Consortium CRADA was provided to CDMRP officials, upon request, for use by other CDMRP-funded consortia.

By 2014, the BADER Consortium completed two rounds of BADER-funded calls for proposals and identified its eighth BADER-funded clinical study. The earliest studies received clearance from the USAMRMC Human Research Protection Office to begin study activities in June of 2013. The Administrative Core provided critical support for these activities by coordinating efforts, in partnership with the EACE, to identify research gap areas used to solicit proposals for BADER-funded projects and assist with the scientific review process. Totaling \$7.6 million in direct project funding, the eight BADER-funded studies have a net planned enrollment greater than 1,400 subjects.

Topic areas covered by BADER-funded projects and their emerging team research initiatives include the following: assessing new, clinically relevant research areas in DoD-identified critical gap areas to reduce the incidence of falls; retraining to improve walking and running after amputation; prescribing prosthetics for work and carrying heavy loads; and determining the impact of robotic prosthetics on functional outcome levels and QoL. Additional projects focus on improving measures of functional outcomes and determining the effectiveness of current rehabilitation care trajectories.

In addition to their assignments on BADER-funded research projects, members of the CRC on-site staff have provided support for 37 non-BADER-funded studies at MTF sites. The nature of CRC staff contributions has been broad. Their responsibilities have included completing literature reviews in preparation of project presentations and publications; recruiting human subjects; assisting with the preparation of grant proposals; monitoring regulatory documents and processes; engagement with clinical staff to promote systematic outcomes assessment; loading research data into the PDMS; and contributing to the evaluation and acquisition of laboratory equipment.

The Scientific and Technical Cores demonstrated the capacity to provide support for orthopaedic rehabilitation research. The cores have supported BADER-funded research projects and provided valuable support and expertise for research ideas that become new research proposals and research areas. The Biomechanics Core supported a multicenter CRSR project to enhance data sharing. The Biostatistics Core provided statistical modeling support for seven external grant applications in the fall of 2014. The Outcomes Core spearheaded two clinical research initiatives and provided assistance to nearly all projects and grant proposals.



**FIGURE 2.** Multiteam System Model indicating five research activity levels. Research initiative partnerships emerge from one or more collaborating organizations at each level joining to form a multiteam research system to address an identified gap in patient care.

At the time of this report, one BADER-funded study has been completed. BADER research efforts have led to five published manuscripts, six pending publications, and 44 published abstracts. Thirteen grant proposals have been submitted to various agencies for external funding. These submissions have resulted in six externally funded projects having a net value of \$3.5 million and an additional \$7.9 million in pending grant submissions.

In 2013, the Defense Health Board (DHB) was tasked with reviewing the full spectrum of amputee care and defining a strategy for preserving and continuing the advancements.<sup>1</sup> BADER Consortium leadership provided one of many DHB briefs and support materials leading to the April 8, 2015, DHB report titled, “Sustainment and Advancement of Amputee Care.” Following an extensive review, the DHB described BADER Consortium as “central to the ARCs’ research capabilities and current efforts.” The DHB also found that the Consortium “significantly enhanced and facilitated” the research capabilities of the ARCs.<sup>1</sup>

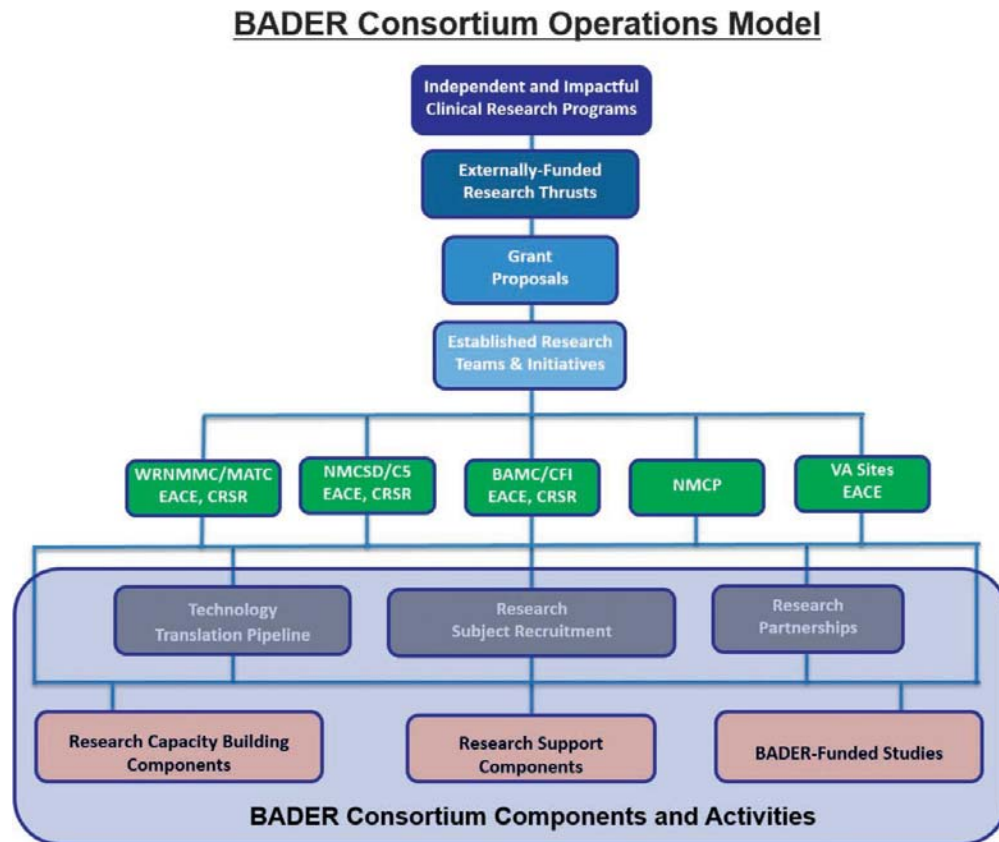
## DISCUSSION

The BADER Consortium is uniquely positioned among its partner programs to advance the orthopaedic rehabilitation research agenda. It uses a clinical research capacity-building

component that supports research team building and the successful identification and establishment of impactful and sustainable research initiatives. Key research infrastructures have been established in support of BADER-funded, externally funded, and MTF-supported clinical research projects. However, not all partner organizations have uniformly embraced Consortium-centric components.

The Consortium CRADA is a Consortium-centric mechanism that is used to rapidly onboard study sites and research projects. It provides a uniform standard operating procedure that addresses the broad range of policies related to research partnerships. Adoption of the Consortium-centric CRADA has been mixed across branches of the military, although readily embraced by academic, industrial, and select government partners. As a result, natural separations have begun to form between Consortium CRADA partners and nonpartners. Such divisions are disadvantageous and Consortium activities would be enhanced by the broad acceptance of a unified CRADA mechanism.

While BADER Consortium’s research infrastructures and project activities are seen as “central” to the ARCs’ mission, they should not be viewed as complete. BADER’s operational model was originally designed to focus primarily in three component areas—capacity-building, research-support,



**FIGURE 3.** Primary (beige shaded) and emerging (gray shaded) components of the BADER Consortium operations model. Green-shaded elements indicate primary collaboration sites (acronym definitions in text). Also shown are the four BADER-supported stages that DoD and VA research sites undergo to obtain research independence and clinical impact.



and initiative-launching studies. As the result of our observations and direct requests for assistance, BADER support has transitioned limited resources to assist with technology translation, research subject recruitment, and research partnership activities (Fig. 3). Clearly, the development and sustainment of large-scale research subject recruitment capabilities focused on military personnel and civilians is an additional desired infrastructure, considering the goal of sustaining world-class research and patient care efforts during periods of reduced conflict.<sup>1</sup>

Streamlining the transition of new technologies into clinical research and patient care is facilitated by an understanding and implementation of the science behind team science.<sup>13</sup> As the breadth of orthopaedic rehabilitation gap areas grows to encompass critical outcomes determinants in clinical acute care and early intervention focus areas, infrastructures for the rapid establishment and sustainment of dynamic research partnerships are also warranted.

## CONCLUSION

The BADER Consortium is a highly effective network for enhancing orthopaedic rehabilitation research capacities at MTF and VA sites, establishing research areas in key gap areas and supporting an array of clinical studies in partnership with government, academia, and industry. Through its partnership with the EACE and cooperative agreement with CDMRP, the BADER Consortium is addressing important gaps in clinical orthopaedic rehabilitation research and patient care. Structures and activities of the BADER Consortium have become “central” to the ARCs’ research capabilities and current efforts to strengthen and sustain evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for wounded warriors.<sup>1</sup>

## ACKNOWLEDGMENTS

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Finally, none of this work would be possible without the courage and drive of wounded warriors whose desire to continue serving and actively engage life is beyond inspirational.

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# The Center for Rehabilitation Sciences Research: Advancing the Rehabilitative Care for Service Members With Complex Trauma

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**ABSTRACT** The Center for Rehabilitation Sciences Research (CRSR) was established to advance the rehabilitative care for service members with combat-related injuries, particularly those with orthopedic, cognitive, and neurological complications. The center supports comprehensive research projects to optimize treatment strategies and promote the successful return to duty and community reintegration of injured service members. The center also provides a unique platform for fostering innovative research and incorporating clinical/technical advances in the rehabilitative care for service members. CRSR is composed of four research focus areas: (1) identifying barriers to successful rehabilitation and reintegration, (2) improving pain management strategies to promote full participation in rehabilitation programs, (3) applying novel technologies to advance rehabilitation methods and enhance outcome assessments, and (4) transferring new technology to improve functional capacity, independence, and quality of life. Each of these research focus areas works synergistically to influence the quality of life for injured service members. The purpose of this overview is to highlight the clinical research efforts of CRSR, namely how this organization engages a broad group of interdisciplinary investigators from medicine, biology, engineering, anthropology, and physiology to help solve clinically relevant problems for our service members, veterans, and their families.

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## OVERVIEW

Between 2001 and 2015, there have been approximately 327,000 cases of traumatic brain injury (TBI), 138,000 incidents of post-traumatic stress disorder (PTSD), and 1,645 service members who have sustained one or more major extremity amputations while serving in Operations Iraqi Freedom, Enduring Freedom, and New

Dawn.<sup>1</sup> The majority of these severe injuries occurred from the effects of blasts,<sup>2</sup> most commonly the result of improvised explosive devices and rocket-propelled grenades.<sup>3</sup> Improved trauma care on the battlefield and throughout the military health care system (MHS) has resulted in historic survival rates,<sup>3</sup> with service members now surviving injuries that in previous wars would have been fatal. Because of the complexity of these wounds and the frequency of multiple, coexisting injuries and impairments, greater challenges now exist for rehabilitation practices.<sup>3–6</sup>

Battlefield survival is only the first step to recovery after a war injury. It is the responsibility of the MHS, the Department of Veterans Affairs (VA), and—arguably—the entire nation to help service members not only survive after injury but thrive as well. Recovery from complex wounds is extremely challenging for patients and families alike. Rehabilitation practices focus on goal setting and improving function through retraining, adaptive strategies, or utilizing novel equipment and assistive technology. The clinics emphasize restoring basic mobility for activities of daily living (e.g., dressing, bathing, and feeding); encompass cognitive training in order to restore speech and communication; focus on return to recreational and sports activities; and provide tools for emotionally reconnecting to one's family, friends, and community. Given the uniqueness of war-related trauma and the desire to see patients thrive after injury, new rehabilitative methods and technology that focus on the military population must be explored.

Wounded service members represent a patient cohort that is relatively young, had high fitness levels before injury,<sup>2</sup> and is highly motivated to return to high-demanding activities.<sup>6</sup> Careful thought and consideration must be given to mitigate the long-term risks of living with a disability for this population, given their relatively young age at time of injury. For example, the incidence rates of diabetes, heart disease, arthritis, and chronic pain are significantly higher in veterans with limb loss than in

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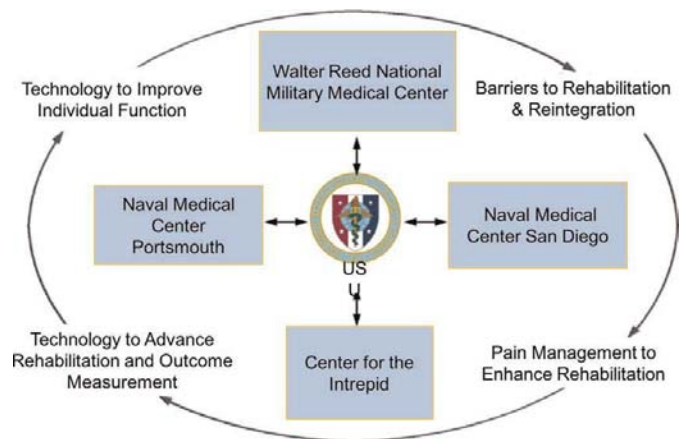


**FIGURE 1.** The CRSR logo highlights the organization's focus on orthopedic, neurologic, and cognitive injuries in service members.

age-matched population controls.<sup>7,8</sup> Thus, research strategies must focus on both the immediate and long-term impacts of wellness and quality of life to mitigate these increased risks.

The Center for Rehabilitation Sciences Research (CRSR) was developed in 2011 to facilitate innovative research projects that promote service member recovery and rehabilitation (Fig. 1). CRSR provides efficient dissemination of research knowledge gained from supported projects to military treatment facilities (MTFs) and the Department of Defense (DoD) Centers of Excellence (CoE). Headquartered at the Uniformed Services University (USU), CRSR has succeeded in developing a well-coordinated interdisciplinary team, primarily forged through partnerships between Walter Reed National Military Medical Center (WRNMMC), Brooke Army Medical Center, the Center for the Intrepid (CFI), Naval Medical Center Portsmouth, and Naval Medical Center San Diego (NMCSD) (Fig. 2). These sites have been the principal MTFs caring for the majority of injured service members returning from combat operations overseas. In addition, CRSR is well positioned, together with the Extremity Trauma and Amputee Center of Excellence (EACE) and other DoD CoEs, to fill the critical gaps in military relevant rehabilitative research identified by the Defense Health Agency and the U.S. Army Medical Research and Materiel Command (USAMRMC). As new discoveries are made, CRSR has the ability to influence the education and training of future health care providers and offer guidance for rehabilitating injured service members and their families.

CRSR is directed by U.S. Army Colonel (Ret.) Paul Pasquina, who served as the Chief of the Integrated Department of Orthopaedics and Rehabilitation at both Walter Reed Army Medical Center and the Naval Medical Center in Bethesda, Maryland, before and during their merger to become WRNMMC. Dr. Pasquina is currently serving as the Chief of Rehabilitation for WRNMMC and the inaugural Chairman of the Department of Physical Medicine & Rehabilitation at USU, which serves as the medical academic institution of the MHS. This new USU department promotes the academic growth of all rehabilitation professionals within the MHS and ensures that the knowledge gained through CRSR and other rehabilitative research centers directly influences resilience and recovery planning.



**FIGURE 2.** A schematic demonstrating the primary research focus areas of CRSR and the primary sites where research is conducted. The center is headquartered at the Uniformed Services University of the Health Sciences.

Although a thorough description and detailed report about CRSR-sponsored projects and its investigators is beyond the scope of this overview, a summary of noteworthy scientific contributions has been included from each of the four research focus areas. This article will highlight CRSR clinical research efforts and how this organization engages a broad group of interdisciplinary investigators and connects them directly with clinicians, patients, and families to help solve clinically relevant problems.

## RESEARCH FOCUS AREA 1: IDENTIFYING BARRIERS TO SUCCESSFUL INTEGRATION

This research area, led by Dr. Seth Messinger, focuses on the use of ethnographic interviewing to identify the current barriers to social reintegration for warfighters with neurological and orthopedic-related trauma. One of the paradoxical challenges facing military clinicians who work in outpatient rehabilitation programs is assessing the quality and effectiveness of intervention strategies. Recent research conducted in the U.S. Armed Forces Amputee Care Program has explored the ways in which the duration of rehabilitation, sense of patient and family autonomy, and locus of control influence the rehabilitative trajectory of severely injured service members. One study compared two patients with similar upper extremity amputations, ages, branch of service, and regional origins. Although both patients excelled at achieving functional goals in rehabilitation, only one had enduring success with his prosthesis;<sup>9</sup> the other abandoned his device. The differing outcomes were attributed to the sense of autonomy/control experienced by the more successful patient in contrast to the less successful one. A follow-on study investigated lengths of stay and expectation concurrences between patients and clinicians and the influence on outcomes.<sup>10</sup> Dr. Messinger identified a critical point beyond which protracted outpatient care may be disruptive as patient concerns shift to other issues and no longer align with those of the therapists. Although these studies are limited in sample size, the depth of ethnographic and qualitative interviewing allows clinical researchers to explore factors that would not otherwise be apparent to the clinical staff.<sup>9</sup>

Limited evidence also is available to understand how the brain is cognitively and psychologically altered after experiencing severe trauma, particularly for those who have sustained both

limb damage and TBI. This gap has been bridged by investigating the nexus of psychiatry and biomedicine as well as their influence on patient participation and success with rehabilitation. To date, 40 patients with both mild TBI and PTSD have been enrolled with unexpected findings discovered. Many subjects self-report that their symptoms of PTSD (e.g., hyper vigilance) could be viewed positively and assist some patients with their transition back into the civilian community.<sup>11</sup>

Finally, ongoing research is focused on understanding the aspects of rehabilitative care that help injured service members develop resilience as they subsequently leave the rehabilitation program and return to duty or their communities. Early results indicate that the relationships these patients form with their providers and peer-visitors have long-lasting effects as they encounter adversities and challenges once resuming life after injury. Their sense of accomplishment during rehabilitation, which they attribute to the knowledge, skills, and motivation given to them by their providers and peers, continues to be a source of inner strength. In addition, patients note that their access to high technology, particularly in prosthetics, not only improves functional abilities but also provides a sense of symbolic commitment that the military and their nation support their recovery. Although many patients report being less physically active in the years after leaving a rehabilitation program, they still greatly applaud the robust clinical focus on sports and athleticism that the rehabilitation program provided. Individuals note that this focus on high levels of performance adds tremendously to their successful community reintegration.<sup>12</sup>

## **RESEARCH FOCUS AREA 2: IMPROVEMENTS TO PAIN MANAGEMENT STRATEGIES**

This research area focuses on pain management strategies critical to recovery and quality of life after severe combat injuries. Drs. Steven Cohen, Jack Tsao and Brad Isaacson lead this area to assist wounded service members with orthopedic and neurological pain relief. For the past several years, research efforts have concentrated on main complications: (1) axial spine pain (2) phantom limb pain (PLP).

### ***Axial Spine Pain: Lower Back and Neck Pain***

Debilitating conditions such as neck and back pain occur more frequently in individuals with limb amputation and trauma and have a more pronounced negative impact on an individual's mobility and quality of life. Low back pain (LBP), in particular, remains a significant challenge to treat in clinical practice. Several studies have demonstrated that LBP is the leading cause of injury in active duty service members and one of the most common reasons for disability worldwide in people under the age of 45.<sup>13,14</sup> By some estimates, the economic costs of treating LBP approach \$100 billion per year in the United States.<sup>15</sup> Similarly, chronic neck pain is a major cause of disability in the world,<sup>16</sup> with a 12-month prevalence rate between 30 and 50%.<sup>16–18</sup> Injured service members also suffer from these conditions at high rates and currently there is no “gold standard” for the treatment of neck pain and LBP. To address this lack of standardization and potentially reduce the economic burden of neck pain and LBP for the DoD and VA, Dr. Cohen has led several double-blinded studies to determine the efficacy of the current standards of care for LBP.

The purpose of one study was to evaluate the best approach for treating patients with lumbosacral and cervical radicular pain. Considerable debate exists as to the benefits of epidural steroid injection (ESI) versus gabapentin prescription.<sup>19</sup> To address these conflicting opinions, Dr. Cohen led a multisite prospective-blinded study to assess whether ESI, conservative treatment, or combination treatment provided the highest patient satisfaction for treating cervical radicular pain. Data from 169 patients suggested no significant differences between these treatment options, but combination therapy improved outcomes compared to stand-alone methods.<sup>20</sup> Dr. Cohen's findings highlight the importance of an interdisciplinary approach to management of pain. These outcomes have implications for treating both injured service members and the general population.

### ***Phantom Limb Pain***

Almost immediately after the loss of a limb, 90 to 95% of all patients with major limb amputations experience a vivid phantom limb sensation such as warmth, cold, itching, pressure, or sense of position.<sup>21</sup> When the sensations become intense enough to be defined as painful, they are referred to as PLP. PLP occurs in 80 to 90% of individuals with limb amputation and usually appears immediately following awakening from anesthesia, though pain onset may be delayed for up to a few days or weeks in 25% of patients. The presence of PLP does not seem to correlate with the cause or location of amputation.<sup>22</sup> In most cases, PLP gradually fades with time, particularly with prosthetic use; however, a significant percentage of patients (30–70%) report having pain that persists for years or decades. Since evidence indicates that pain continuing for longer than 6 months is the most difficult to treat,<sup>22,23</sup> better evidence is needed to identify effective treatment strategies.

The causes of PLP and nonpainful phantom sensation are not known; however, both peripheral and central processes are implicated.<sup>24</sup> Memories of the limb's posture and form before amputation often survive in the phantom.<sup>25,26</sup> After a period of several weeks, a patient's phantom limb may fade from consciousness and/or disappear completely. However, PLP is remarkably difficult to treat, and there are several reports of failed drug trials in clinical literature.<sup>23,24</sup>

Dr. Jack Tsao leads CRSR's PLP research using a combination of virtual reality-based training, simulators, biological assays, and advanced neuroimaging to further understand this debilitating condition. He and his team completed the first randomized, sham-controlled prospective trial of mirror therapy for the treatment of PLP. Mirror therapy functions by having the amputee place a mirror between the intact and amputated limbs while simultaneously moving the phantom limb to mimic the movements of the intact limb viewed in the mirror. Dr. Tsao's team is currently performing a functional magnetic resonance imaging study to determine activation patterns in the brain before and following mirror therapy.

This team has also extended the theory that visual observation is the key to mirror therapy by demonstrating that bilateral amputees with PLP may experience pain relief by observing someone else's limbs moving. In a study of 20 bilateral lower limb amputees with PLP, direct visual observation significantly reduced PLP in both limbs, whereas mental visualization methods were not significant.<sup>27</sup> This inexpensive technique may assist service members with limb loss reduce their pain thresholds and positively influence their ability



to participate in rehabilitation regimens. Additional work is being conducted by Dr. Tsao's team to determine if genetic factors influence PLP since some individuals do not develop this debilitating condition following limb amputation, whereas others are severely affected. Lastly, studies are being conducted to determine how many sessions of mirror therapy are needed for pain relief and whether existing neuropathic pain models are applicable for treating PLP.

### **Heterotopic Ossification**

Heterotopic ossification (HO) is a pathologic process characterized by ectopic osseous growth in muscle and/or periarticular regions.<sup>28</sup> Although HO may develop from rare genetic disorders, abnormal bone growth has been most frequently reported following trauma, arthroplasty, burns, spinal cord injury, and traumatic brain injury.<sup>28</sup> While, most cases of HO in the general population are clinically asymptomatic, and do not require surgical intervention, military service members injured by blasts in Afghanistan and Iraq, have much different prognosis.<sup>29,30</sup> Armaments such as improvised explosive devices (IEDs) and rocket propelled grenades (RPGs) generate extensive polytrauma, and approximately 63% of warfighters with limb loss have developed post-traumatic HO (with 20% to 40% requiring surgical excision).<sup>31,32</sup> Symptomatic HO is problematic for service members since it delays rehabilitation regimens, causes pain, limits range of motion, and requires modifications of prosthetic limbs.<sup>32,33</sup>

The CRSR is committed to understanding the etiology of these ectopic osseous masses and improving surgical planning for servicemen and women. Dr. Brad Isaacson is the lead investigator and received two Congressionally Directed Medical Research Programs (CDMRP) grants (W81XWH-12-2-0017 and W81XWH-16-2-0037) and private donations from the Wounded Warrior Amputee Softball Team to advance this field of orthopedics/rehabilitation. Data from his laboratory has demonstrated a link between bench top research and bedside care, with the mineral apposition rate (MAR), a hallmark for bone growth, computed to be 1.7 times faster in trauma-induced HO compared to non-pathological human bone.<sup>29</sup> Further, when data from this cohort of wounded warriors was limited to patients with no more than a two-year period from injury to excision, and known correlates (traumatic brain injury and nonsteroidal anti-inflammatory drugs), the MAR and recurrence severity were significantly related.<sup>29</sup>

Research by Dr. Isaacson and his team will now focus on developing a translatable animal model to investigate combat-related factors which have been associated with ectopic bone growth (tourniquets,<sup>34</sup> wound vacuum usage, bioburden, and trauma).

### **RESEARCH FOCUS AREA 3: APPLICATION OF NEW TECHNOLOGIES TO ADVANCE REHABILITATION AND PERFORMANCE**

CRSR supports and enhances existing clinical programs at the MTFs by facilitating the use of new technologies for rehabilitation and performance optimization. A strong partnership has been forged with the MHS, VA, and EACE to help provide infrastructure and personnel support for research projects. Efforts within this research area are led by a team of principal investigators, including Drs. Erik Wolf, Brad Hendershot, Alison Pruziner, Jason Wilken, Christopher Rábago, Elizabeth Russell Esposito, and Ms. Marilynn Wyatt. Advanced evaluation and treatment techniques

are applied to help service members regain functionality after physical and cognitive injuries and to understand the longer-term implications of such injuries and rehabilitation processes.

Novel rehabilitation techniques applied in multisensory virtual reality environments (VRE) promote resilience and recovery to improve physical and cognitive skills in wounded service members.<sup>4</sup> There are four high-end VRE (Computer Assisted Rehabilitation Environment, Motekforce Link, The Netherlands) used in the MHS to provide a safe, interactive setting for clinicians to simulate community, recreational, or occupational tasks.

Dr. Wolf led a CRSR effort to determine the most beneficial biomechanical and physiological feedback modalities within a VRE for delivering physical therapy to injured service members. Preliminary results indicate that a game-style application that provides feedback to the patient in an indirect manner produces the most positive outcomes. In collaboration with Dr. Wolf's efforts, Drs. Pruziner and Hendershot are utilizing a VRE to identify how dual tasking with increased cognitive demand affects walking ability for people with unilateral lower limb amputation. Previous research has shown that performing tasks requiring divided attentional resources result in abnormal gait mechanics. Preliminary analyses suggest individuals with amputations may differentially prioritize cognitive and motor processes when walking. This study has potentially important implications regarding the ability to fully participate in a person's natural environment after limb loss, and also may relate to an increased risk of falling. Additional ongoing efforts are aimed at evaluating biomechanical and cognitive responses to walking in more ecologically valid VRE, as opposed to game-style environments, which will include additional challenges to working memory, decision-making, and navigational skills.

Optimizing performance and maximizing functional outcomes are critical components of a rehabilitation program and are synonymous with returning to active duty for many wounded service members. Drs. Wilken and Rábago implemented an assessment battery within a militarized VRE to identify functional and cognitive deficits that emerge when performing military-specific tasks. This study incorporates load carriage, variable terrain negotiation, and quick decision-making. Physiological and biomechanical data collected during these tasks can guide future therapies and the prescription of prosthetic or orthotic devices for service members with lower extremity injuries. This study is the first step in developing a military-relevant assessment battery with objective performance metrics that correlate to return to duty rehabilitation goal. Follow-up studies supported by CRSR will incorporate the knowledge gained from the assessment study into a VRE-based, military-specific treatment intervention aimed at returning injured service members to duty and increasing military readiness.

In addition to VRE-based rehabilitation, other studies within this focus area seek to understand secondary musculoskeletal complications of limb loss and the influences of various technologies and rehabilitation paradigms. As noted, LBP is especially prevalent among persons with amputation(s), perhaps related to altered gait and movement patterns. To better understand these specific risk factors, Dr. Hendershot has performed several retrospective studies using the large biomechanical database at WRNMMC to directly quantify how gait deviations influence trunk and spine motion among service members with lower limb loss. Notably, larger and asymmetric trunk

motions with amputation were associated with increased loading at the lower back during walking<sup>35</sup> and sit-to-stand movements.<sup>36</sup> Although these increases were of small-moderate magnitude, repeated exposures over time may predispose these individuals to LBP onset and recurrence.<sup>37</sup> Ongoing and future research will investigate the origins of altered trunk motion and subsequently assess methods or devices to minimize these loads in an effort to mitigate the prevalence of LBP among service members with lower limb amputation.

Another secondary musculoskeletal complication of unilateral limb loss is osteoarthritis (OA) within joints of the intact limb. Persons with unilateral lower limb amputation tend to preferentially use their intact limb during gait and movement, which leads to larger and more prolonged forces applied to the intact knee and/or hip joints. CRSR has funded two retrospective studies to assess gait mechanics in individuals with transtibial and transfemoral limb loss to determine how the intact limb is loaded at various time points during the rehabilitative process. Excessive intact limb loads (relative to controls) were only present at early time points among people with transtibial amputation, but persisted through late rehabilitation for persons with transfemoral amputation.<sup>38</sup> Such evidence suggests an increased risk for early onset of OA and supports the development and assessment of interventions to correct modifiable gait mechanics in this population. A prospective evaluation of knee loading has been initiated to begin to address this gap.

In order to assist with multisite efforts aimed at sharing and combining commonly used biomechanical data across the MTFs, CRSR supported a project to evaluate the intra- and interlab reliability of gait data obtained at WRNMMC, CFI, and NMCS. <sup>39</sup> Ten participants traveled to each site to complete three biomechanical gait evaluations according to each laboratory's standard operating procedures. Data were analyzed by a third party to eliminate bias. Results indicated that these measurements were highly reliable both within and between laboratories, with mean kinematic errors less than 5 degrees across all joints and planes of motion, and mean kinetic errors less than 10% for all joint moments. The ability to collect reliable biomechanical data at these three major facilities will support future multisite studies and data sharing.

**RESEARCH FOCUS AREA 4: TRANSFER OF NEW TECHNOLOGY TO IMPROVE INDIVIDUAL PERFORMANCE AND FUNCTIONALITY AFTER INJURY** Novel devices, including prosthetics and orthotics, help return service members with cognitive and physical trauma to independent function. Previous research supported by CRSR and USAMRMC compared passive energy-storing and return (ESR) prosthetic feet with a powered ankle foot prosthesis to determine, which novel technology could provide the highest quality of life and expedite rehabilitation regimens.<sup>40</sup> Results indicated that the powered device had a larger range of motion and generated more power during the preswing phase of gait as compared to the energy storing and return,<sup>40</sup> demonstrating how powered devices may assist those with limb loss improve their gait. Ongoing studies continue to examine the effects of advanced prosthetic components, including microprocessor and power knee prosthetics.

In addition to examining prosthetic components, orthotic devices are being evaluated to determine their efficacy for improving gait in injured service members with extremity trauma and limb salvage. Recent initiatives by Drs. Wilken and Russell Esposito systematically modified several mechanical parameters of

an ankle-foot orthosis to identify optimal design and prescription criteria for various terrains.<sup>41,42</sup>

Because of the high incidence of upper limb loss occurring in combat casualties, focused research has been needed to improve prosthetics and control strategies for individuals with upper limb amputation. CRSR partnered with the Alfred Mann Foundation (<http://aemf.org>) to conduct a clinical trial through the Food and Drug Administration (FDA) entitled, "First-in-man demonstration of a fully implanted myoelectric sensors system to control an advanced electromechanical prosthetic hand."<sup>43</sup> A significant limitation to current myoelectric devices is their dependence on surface skin sensor electrodes to control their actuation. Unfortunately, these sensors are often unreliable, especially when individuals perspire or when their prosthetic socket moves in different positions. In addition, surface electrodes are limited in that they can only detect superficial muscle activity and do not provide the user with enough intuitive control. This collaborative study demonstrated the feasibility of implanting wireless electrodes in the forearm of service members with transradial amputation to control a 3-degrees-of-freedom prosthetic hand. Future work will include expanding the use of this technology for individuals with transhumeral level amputations.

Expanding on the field of upper extremity prosthetics, CRSR is also proud of its partnership with the Defense Advanced Projects Agency (DARPA) to evaluate the performance of the DEKA arm ([http://www.dekaresearch.com/deka\\_arm.shtml](http://www.dekaresearch.com/deka_arm.shtml)). This revolutionary multiple degrees-of-freedom prosthetic arm has received FDA approval and is the first of its kind to help pioneer the intersection between robotics and improving human performance for individuals with disabilities. CRSR also works with DARPA and other academic and industry groups to utilize novel neuroprosthetics to help restore sensory/haptic feedback for prosthetic users. Our research portfolio is bolstered by strong partnerships with teams, such as the Human Engineering Research Laboratories ([www.herl.pitt.edu](http://www.herl.pitt.edu)), which have helped collectively develop a specialized patient-controlled analgesia device adapter to improve postsurgical pain, autonomy, and independence for patients who have lost the use of their limbs, enabling them to participate in rehabilitation.

**CONCLUSION** The clinical research community has an obligation to address the needs of these service members and veterans with complex orthopedic and neurological injuries stemming from recent conflicts. Injuries to young military service members, particularly those caused by blasts, pose unique challenges to rehabilitation that require research programs and consortia to help advance science and care. CRSR is dedicated to not only identifying gaps in the research but also to aligning resources in a synergized fashion to define and validate the most effective rehabilitation strategies for this patient population. CRSR engages a broad group of interdisciplinary investigators from medicine, biology, engineering, anthropology, and physiology and connects them directly with clinicians, patients, and families to help solve clinically relevant problems for our service members, veterans, and their families.

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# Improving Outcomes Following Extremity Trauma: The Need for a Multidisciplinary Approach

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**ABSTRACT** Extremity injuries contribute a significant amount to the overall disability of combat-injured soldiers. Tracking patient outcomes allows military health care providers to gain a better understanding of the disability associated with various injury patterns. Only recently have orthopedic surgeons begun to collect functional outcome measures, and perhaps even more importantly, have begun to collect patient-reported outcomes. There is a growing body of evidence demonstrating the importance of a multidisciplinary approach to optimize outcomes in patients following severe extremity trauma. Tracking the outcomes of these interventions longitudinally will ultimately provide the military surgeon with an evidence-based plan to treat severe combat-related extremity injuries, leading to optimal care for future combat injured patients.

“However beautiful the strategy, you should occasionally look at the results.”—Winston Churchill

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## INTRODUCTION

Extremity injuries contribute a significant amount to the overall disability of combat-injured soldiers. For soldiers undergoing a physical evaluation board for unfitting conditions caused by a battlefield injury, 3 out of the top 5 and 6 out of the top 10 are orthopedic/extremity conditions.<sup>1</sup> Furthermore, 57% of combat-injured soldiers had unfitting conditions that were only orthopedic. Of soldiers medically evacuated with a head, thorax, or abdominal injury with a concomitant orthopedic injury, the orthopedic injury was the primary unfitting condition in over 75% of the patients.<sup>1</sup> In a follow-up study consisting of a cohort of these patients whose primary unfitting condition was osteoarthritis, it was directly attributable to combat injury in 92% of cases and occurred in as little as  $19 \pm 10$  months following the injury.<sup>2</sup> This necessitates direct attention to examining lessons learned related to orthopedic injury so that every effort is made to optimize the functional recovery of soldiers injured in future conflicts. As the nation transitions to an interwar period, it provides an ideal time to reflect on the advances in the treatment of severe extremity injuries to identify “lessons learned” that will ultimately result in improving the military health care capability for the next conflict.

## IMPORTANCE OF TRACKING OUTCOMES

Patient outcomes help military health care providers understand disability. Although the desired outcome is to return a patient to his or her maximal level of function, historically, orthopedic outcomes focus on factors such as radiographic

union, alignment, development of arthritis, and the presence of postoperative complications such as infection. Only recently have orthopedic surgeons begun to collect functional outcome measures, and perhaps even more importantly, have begun to collect patient-reported outcomes.

The extreme value of collecting relevant outcomes assessments was identified early during the conflicts and at the same time, the inherent difficulties with doing so were realized to include additional time and infrastructure requirements. However, there is still a significant need for more relevant surgical outcome assessments to assist in guiding difficult decision-making, such as the decision to amputate or attempt limb salvage in the severe extremity injury.<sup>3</sup> However, as we have entered a low volume combat casualty flow era, it can provide an opportunity to evaluate the outcomes achieved from the conflicts more thoroughly in an attempt for us, as providers, to continue to learn and improve.

When examined closely, patients do not do as well as initially perceived by their physicians. For example, Lebrun et al recently reported long-term outcomes of patients with a relatively simple fracture (patella) treated operatively.<sup>4</sup> Even at 6.5 years following surgery, patients still had significant functional deficits despite the fracture being healed. Extension power and Biodex dynamometric testing revealed deficits of a quarter to one-third of the uninjured contralateral extremity. In addition, over half of the patients required an additional surgery due to symptomatic hardware.<sup>4</sup> This study highlights the fact that even with a simple fracture pattern that goes on to radiographic union following surgery, patients can still have significant long-term functional deficits as a result of their injury.

Now, consider the effects seen with more severe extremity trauma, such as those resulting from combat. In a large prospective observational study, the Lower Extremity Assessment Project (LEAP) Study Group showed the long-term consequences of severe lower extremity trauma in a civilian population. At 7 years following injury, just over one-third

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(34.5%) of patients had a physical Sickness Impact Profile (SIP) subscore typical of the general population of similar age and gender.<sup>5</sup> Furthermore, out of those who worked before their injury, only 58% returned to work 7 years later. Even worse, of those who return to work, patients are limited in their performance 20 to 25% of the time.<sup>6</sup> These data are similar to what has been seen in the military population following severe combat extremity injuries. In a retrospective cohort study of 324 Service Members who underwent amputation or limb salvage following a combat-related extremity injury, Doukas et al reported that at an average follow-up of 38.6 months only 43.7% had returned to work and 19.9% had pain interfering with daily activities.<sup>7</sup> These data demonstrate that similar challenges are seen long-term in patients, whether civilian or military, with severe lower extremity injuries.

### **THE NEED FOR A MULTIDISCIPLINARY APPROACH**

In assessing outcomes of patients that sustained high-energy lower extremity trauma, O'Toole et al showed that surgeons and patients rarely agree on outcomes, as infrequently as  $\leq 25\%$ , which highlights the complexity of synthesizing outcomes based research.<sup>8</sup> Perhaps, surgeons should not just focus on treating the injury, but treating the individual patient as well. As Cannada and Jones highlighted in their review of the LEAP Study Group's findings, a patient's personality is not significantly influenced by changes in the patient's life circumstances, i.e., the significant trauma they just experienced.<sup>9</sup> However, as eluded to by Levin et al, failure to recognize the difference between treating an illness and a disease may be one explanation for the vast differences in outcomes seen following injury.<sup>10</sup> Knowing this, could it be possible to predict which patients are going to do worse and intervene early to optimize their outcome?

A vitally important lesson learned is establishing realistic expectations for pain management, specifically noting that patients with severe lower extremity injuries may heal their bone and soft tissue injuries, but pain will frequently persist.<sup>11–13</sup> In most cases, the bone heals, and, in some cases, there are complications. However, there remains a large degree of uncertainty as to why some patients do so much better than others, when the bone healed in good alignment and there were no postoperative complications. It has been shown that “negative mood,” specifically anxiety, plays an important role in the persistence of acute pain and both pain and depression correlates with patient satisfaction in those who have sustained severe lower extremity trauma.<sup>14,15</sup> When evaluating predictors of disability and pain following musculoskeletal injuries, Vranceanu et al found that catastrophic thinking at 1 to 2 months postinjury was the sole significant predictor of pain at rest, pain with activity, and disability at 5 to 8 months.<sup>16</sup> The physician must understand and recognize the impact that these factors can play in a patient's rehabilitation process to optimize their outcome.

However, one of the most important advances in pain management during the recent conflicts can easily be summed up in the phrase “multimodal pain management.” In addition to the use of various intravenous and oral pain medications, the benefits of advanced regional anesthetics, delivered through continuous peripheral nerve catheters, were quickly realized. In many patients with severe extremity injuries or amputations, these were placed before transport back to the United States. These peripheral nerve catheters can provide the analgesia needed to make smooth transitions between the often, frequent, interval debridement and irrigations until the definitive surgery can be safely performed, while minimizing the need for intravenous or oral narcotic pain medication.<sup>12</sup> As mentioned by Pasquina and Shero, rehabilitation needs to start in the acute care setting. The Amputee Patient Care Program, which encourages collaboration among various services, to include pain management, encouraged this to happen.<sup>13</sup>

These studies highlight the fact that some patients may need more than just an orthopedic surgeon, following their fracture to union, to maximize their outcome. Archer et al found that 85% of patients reported a need for at least one vocational, behavioral health, or other support service following severe lower extremity trauma, and 32% had an unmet need over the course of the first year.<sup>17</sup> The highest need unmet was for behavioral health and vocational services. Patients with a perceived unmet need have worse outcomes.<sup>17</sup> The military has done well in meeting patients' needs based on holistic care models, e.g., the Armed Forces Amputee Patient Care Program and newer interdisciplinary programs for combat injured undergoing limb salvage.<sup>11,13,18–22</sup>

Quality data come from the LEAP Study Group, specifically informing orthopedic surgeons on outcomes related to high-energy musculoskeletal trauma.<sup>5,23</sup> When comparing amputation to limb salvage, the authors found no difference in SIP scores at 2 and 7 years. The SIP assesses patients' dysfunction through everyday behavior capturing the physical, mental, and social aspects of health-related function. Another important finding from the LEAP Study Group's research was the identification of several predictors of poor outcome, regardless of group (amputation vs. limb salvage) to include a poor social support network and low self-efficacy.<sup>5,23</sup> This reinforces the importance of an individualized interdisciplinary approach to treating patients with severe extremity injuries. This is especially important when counseling patients on possible courses of action as surgeons cannot rely on current lower-extremity injury severity scoring systems because they have been shown not to be predictive of functional recovery of patients who undergo reconstruction.<sup>24</sup>

The best available data from the military are from the Military Extremity Trauma Amputation/Limb Salvage study, which found better functional outcomes in patients with amputation compared to limb salvage.<sup>7</sup> However, when interpreting these results it is important to look more closely

at the data before concluding that amputation is superior. Patients were included in the Military Extremity Trauma Amputation/Limb Salvage study if their injury occurred between 2003 and 2007.<sup>7</sup> During this period, there was a patient-centric rehabilitation program for amputees (The Armed Forces Amputee Patient Care Program), but, until late 2008, there was no such similar program for patients with limb salvage. In another retrospective comparison, service members with early amputation improved in several areas to include psychiatric diagnoses, but it is also important to note that they had more outpatient visits for psychiatry, occupational therapy) and physical therapy.<sup>25</sup> Before acceptance of these results as definitive evidence the following question must be answered, “Did amputees do better compared to those service members who underwent limb salvage because they received more attention and more support?”

In answering this question, it is helpful to further define the clinical problem and answer the questions, “How many patients fail limb salvage and why?” Stinner et al initially reported that 15% of amputations occurred more than 90 days following injury, with many of those occurring more than a year after injury.<sup>26</sup> A comprehensive analysis by Krueger et al determined that during the first 10 years of conflicts in Afghanistan and Iraq, approximately 10% of all amputations were performed more than 90 days following injury.<sup>27</sup> The 90-day time period was chosen to take into account time to attempt limb salvage. When evaluating outcomes of combat-related type III open tibia fractures, Huh et al found that those undergoing late amputation had several common characteristics: (a) more flaps, (b) higher rates of infection (both deep soft tissue and osteomyelitis), and (c) more reoperations.<sup>28</sup> This is similar to data reported by the LEAP Study Group, who noted that patients undergoing limb salvage for a mangled foot and ankle were likely to have a longer time to full weight bearing and more rehospitalizations. In addition, those that went on to an ankle arthrodesis (fusion) or required a free flap for soft tissue coverage were likely to have worse outcomes.<sup>29</sup> Optimizing the management of these severe injuries to minimize the post-operative complications that more commonly lead to poor outcomes should be a focus of future research efforts.

## SUMMARY

Ultimately, the surgeon should be armed with an evidence-based plan to treat severe combat-related extremity injuries and patients must be given the individualized tools to succeed. For some, the tools to succeed may simply be following their fracture to union with periodic clinic visits to be reassured that they are on the right path. For others, it may consist of custom orthotics and/or intense physical therapy.<sup>5</sup> And, yet, for others, it may be a wide range of vocational, behavioral health, and other social support services to optimize their individual outcome.<sup>9</sup> Military treatment facilities have recognized the importance of this and have established well rounded integrated rehabilitation programs that are

pushing beyond the boundaries of traditional rehabilitation, which is resulting in improved outcomes for injured servicemen and women.<sup>3,11–13,18–22</sup>

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# The Prevalence of Gait Deviations in Individuals With Transtibial Amputation

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**ABSTRACT** Individuals with a transtibial amputation (TTA) are at increased risk for developing secondary musculoskeletal disorders as a result of multiple gait deviations. These deviations are primarily characterized using group mean comparisons, which do not establish if deviations are prevalent, of large magnitude, or both. In contrast, use of normative reference ranges and prevalence specifically identifies the percentage of individuals outside of a predefined acceptable range. The purpose of this study was to identify and characterize gait deviations in service members with unilateral TTA using group mean comparisons and normative reference ranges (able-bodied mean  $\pm$  2 SD). Temporal spatial, kinematic, and kinetic data were collected during biomechanical gait assessments of 40 able-bodied males and 16 males with a TTA. Highly prevalent and statistically significant deviations were observed at the ankle and knee of the prosthetic limb and hip of the intact limb in the TTA group. Approximately 20% of measures that were significantly different between groups demonstrated 0% deviation prevalence. Deviations in the prosthetic limb were in agreement with literature, although most intact limb deviations were not. Further study is needed to determine the exact etiology of these deviations, and their association with the development of secondary musculoskeletal conditions.

## INTRODUCTION

Individuals with lower extremity amputations are at increased risk for developing secondary musculoskeletal disorders as a result of persistent gait deviations associated with prosthetic use.<sup>1</sup> Compared to age-matched peers without amputation, World War II veterans with transtibial amputation (TTA) showed an increased incidence of knee and hip osteoarthritis later in life (mean age = 71.8 years); 30 to 35 years after their amputation.<sup>2,3</sup> Individuals with a unilateral TTA were also 88% more likely to develop osteoporosis in the amputated limb compared to the general population.<sup>4</sup> In addition, 60% of individuals with a TTA reported the onset of back pain within 2 years of amputation and 63% categorized pain as moderate to severe.<sup>5</sup> Gait deviations and compensations such as asymmetric single limb stance time<sup>1,6</sup> and increased vertical ground reaction forces at the intact limb<sup>3,7-9</sup> are thought to exacerbate these musculoskeletal degenerative processes. Early identification of gait deviations and formal training of gait mechanics, especially in young individuals with a TTA, could help prevent a lifetime of poor gait mechanics and reduce the risk of developing secondary musculoskeletal conditions.

Few studies have systematically determined the effect of a TTA on temporal spatial, kinematic, and kinetic measures on a per person basis. Gait deviations are often characterized using group mean comparisons of individuals with a TTA to able-bodied (AB) participants.<sup>10-17</sup> However, individuals

with a TTA in these studies often vary considerably in age (20–77 years) and prosthetic experience (1–59 years),<sup>11,12,15,16</sup> which may reduce statistical power because of increased inter-subject variability.<sup>18</sup> A reduction in statistical power lessens the probability that significant differences (i.e., deviations) will be detected. Further, many of these studies have fewer than 10 participants,<sup>10,13-17,19</sup> which limits rigorous statistical analysis.<sup>19</sup> To achieve statistical significance using group mean comparisons, a high proportion of values from the TTA group must be consistently greater or less than the AB group mean; or a few individuals with a TTA must have sufficiently large deviations to bias their group mean. As a result, the reader is often unable to determine if a given deviation is prevalent, of large magnitude, or both.

An alternate approach for identifying gait deviations in individuals with a TTA is to compare their data against normative reference ranges (NRR), which are calculated using mean and variability data from an AB group.<sup>20</sup> A value from an individual with a TTA that falls outside the NRR is considered a deviation in that specific measure. Prevalence of deviations in each measure can then be determined as the percentage of a population that functions outside the established NRR.<sup>20-23</sup> Deviations identified using a NRR approach are indicative of abnormal mechanics in each individual, which may be missed when comparing the mean performance of a patient population to mean performance of an AB group. Further, prevalence provides an easy-to-understand metric, which indicates the frequency of deviations, not described using traditional group mean comparisons.

The prevalence of gait deviations, as identified using a NRR approach, has yet to be determined for a group of individuals with TTA. The combination of both group mean comparisons and prevalence data could be used to identify gait deviations most likely encountered when treating individuals with a TTA. Therefore, the purpose of this study

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was to determine the presence of gait deviations and their prevalence in a group of service members with a TTA.

## **METHODS**

### **Subjects**

Data from 40 AB males and 16 male individuals with a TTA are presented in this study. The AB group included service members between the ages of 18 and 45 years with no pain at time of data collection and no history of lower extremity injury requiring surgery. The TTA group included service members between the ages of 18 and 45 years who used an energy-storing-and-returning ankle-foot prosthesis, were able to ambulate without an assistive device, and had been ambulating for approximately 4 months. In order to detect deviations not associated with acute pain, the TTA group could not have pain of greater than 4 out of 10 anywhere on their body at the time of data collection. The TTA group was a convenience sample of patients within a military treatment facility who met the inclusion criteria without bias toward their mechanism of injury or level of physical fitness. All participants provided written informed consent before participating in this institutional review board–approved study.

### **Procedures**

Participants underwent a biomechanical gait assessment on level ground at a predefined walking speed scaled to leg length using a Froude number<sup>24</sup> of 0.16. A full-body, six-degree-of-freedom marker set comprised of 57 retroreflective markers was placed on 13 body segments.<sup>25</sup> A 26 camera motion capture system (Motion Analysis Corp., Santa Rosa, California) recorded marker trajectories as participants walked across a 10-m walkway embedded with eight AMTI force plates (AMTI, Inc., Watertown, Massachusetts) operating at 1,200 Hz. Temporal spatial, kinematic, and kinetic data were normalized to 100% step cycle using Visual 3D (C-Motion Inc., Rockville, Maryland). Five representative strides from each participant were exported into MATLAB (Mathworks, Natick, Massachusetts). Key kinematic and kinetic measures for the ankle, knee, hip, pelvis, and trunk were defined as previously described.<sup>25</sup> Joint range of motion (ROM) was defined as the difference between the maximum and minimum joint angle values during one gait cycle. On the prosthetic side, ankle sagittal ROM was defined as the difference between the maximum and minimum joint angle values during stance.

Temporal spatial measures were determined using kinetic gait events and foot kinematics. Step length was defined as the distance between the foot centers in the anterior-posterior direction at heel strike. Step width was calculated as the medial-lateral distance between the heel markers on each foot during double-limb stance. Step time was quantified as the duration between heel strike of the ipsilateral limb and heel strike of the contralateral limb. Stance time was determined as the duration between heel strike and toe off of the same limb. Swing time was quantified as the duration

between toe off and heel strike of the same limb. Stride length was defined as the distance between the foot centers in the anterior-posterior direction on successive heel strikes of the same limb. Stride time was quantified as the duration between successive heel strikes of the same limb.

### **Statistical Analysis**

SPSS v.19 (SPSS Inc., Chicago, Illinois) was used for all statistical analyses. AB and TTA group means and standard deviations were calculated for demographic, anthropometric, temporal spatial, kinematic, and kinetic measures. Due to differences in sample size, and a desire to retain all available data, Mann–Whitney non parametric tests were used to identify differences between AB and TTA groups for demographic-anthropometric, temporal spatial, and kinematic-kinetic measures. The AB group's right lower limb was used in comparisons made to the TTA group's lower limbs (e.g., AB vs. prosthetic limb and AB vs. intact limb). Bonferroni–Holm corrections were performed to correct for multiple comparisons across all measures. The Bonferroni–Holm method uses a step-down approach to account for multiple comparisons by arranging *p* values from the smallest to the largest and comparing them to sequential significance cutoffs.<sup>26</sup> Significance was set at a *p* value of 0.05. Thus, correction factors accounting for 6, 6, and 53 comparisons yielded minimum *p*-value cutoffs of 0.0083, 0.0083, and 0.0009 for demographic-anthropometric, temporal spatial, and kinematic-kinetic measures, respectively.

Similar to the work of O'Sullivan,<sup>20</sup> the NRR for each measure was defined as two standard deviations greater than and less than the AB group mean. Microsoft Excel 2007 (Microsoft Corp., Redmond, Washington) was used to determine the upper and lower bounds of the NRR for the AB group and the prevalence of deviations in the TTA group. The deviation prevalence for each measure was calculated as the percentage of participants from the TTA group with individual mean values outside the NRR. To facilitate visualization of the data and ease of presentation, prevalence values were categorized into three groups; high (>50%), moderate (25–49%), and low (<25%).

## **RESULTS**

Participant demographics and anthropometrics including age, height, weight, body mass index, leg length, walking speed, and time since independent ambulation (TTA group only) are listed in Table I. Only age demonstrated a significant difference between groups with the TTA group being an average of 4 years older than the AB group (*p* = 0.006). Figure 1A provides an example of a measure that demonstrates high deviation prevalence in the TTA group with significant between group difference; 5.4% of all measures presented here were in this category. In addition, 7.1% of measures showed moderate deviation prevalence in the TTA group with significant between group differences (Fig. 1B)

**TABLE I.** Demographic and Anthropometric Measures for AB and TTA Groups

Mean (SD)	Age (years)	Height (m)	Weight (kg)	BMI (kg/m <sup>2</sup> )	Leg Length (cm)	Walking Speed (m/s)	Ambulation (weeks)
AB	24.1 (6.5)*	1.7 (0.1)	77.2 (10.8)	25.4 (3.1)	91.8 (5.9)	1.20 (0.04)	N/A
TTA	28.5 (5.4)*	1.8 (0.1)	86.6 (12.4)	27.4 (3.0)	93.3 (6.1)	1.21 (0.04)	16.6 (3.3)

BMI, body mass index; Ambulation, time since independent ambulation. \*Significant between group difference after Bonferroni–Holm correction with smallest  $p$ -value cutoff of 0.0083.

and 12.5% showed moderate deviation prevalence in the TTA group without significant between group differences (Fig. 1C). Lastly, 17.9% of measures had low deviation prevalence in the TTA group with significant between group differences (Fig. 1D) and 57.1% had low deviation prevalence in the TTA group without significant between group differences (Fig. 1E). Kinematic, kinetic, and temporal spatial measurement means and SDs for the AB and TTA groups are shown in Table II. The direction of significant differences between the AB and TTA groups and prevalence of deviations in the TTA group is detailed in Table III.

### Temporal Spatial

In the TTA group, swing time was significantly decreased in the intact limb and moderately prevalent. Intact limb step time and step length measures had the greatest prevalence of deviations among temporal spatial measures (37.5–43.8% respectively), but were not significantly different from the AB group. In addition, 7 of the 16 individuals demonstrated deviations of both step length and step time in the prosthetic

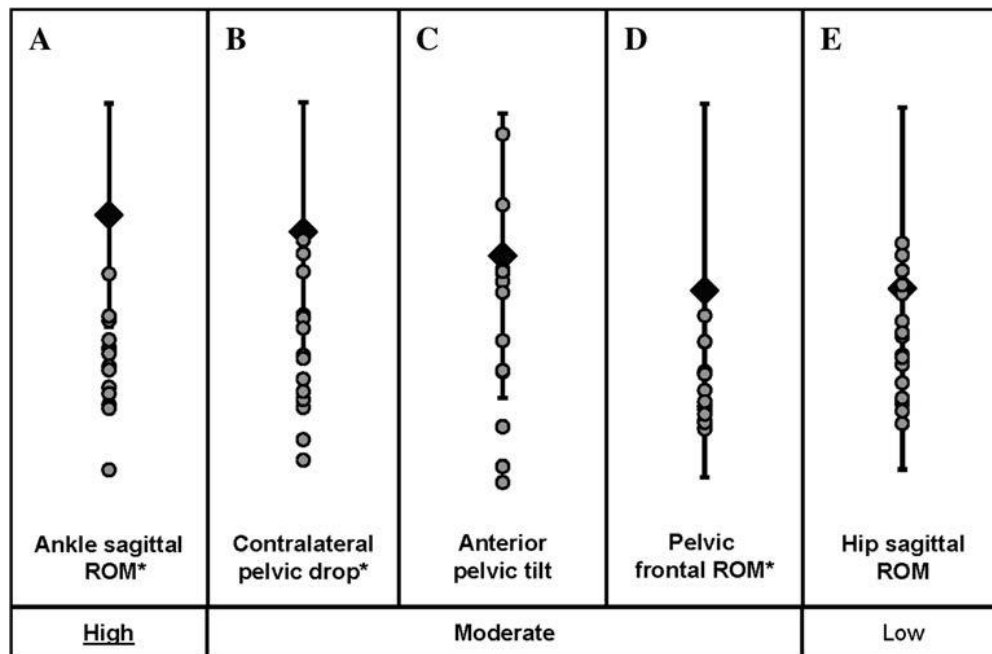
or intact limb. However, step length and step time did not systematically increase or decrease relative to the AB group.

### Ankle

Prosthetic ankle plantarflexion during initial swing, sagittal ROM, and power generation at terminal stance were significantly decreased ( $p \leq 0.001$ ) in the TTA group compared to the AB group with 100, 81.3, and 50% prevalence, respectively. With the exception of initial contact power absorption (43.8% deviation prevalence,  $p \leq 0.001$ ), all intact ankle measures had less than 13% deviation prevalence in the TTA group. Bilateral dorsiflexion moments were significantly different ( $p \leq 0.001$ ) than the AB group, but only with a 12.5% prevalent in the TTA group.

### Knee

Midstance power generation at the intact knee of the prosthetic limb was significantly decreased ( $p \leq 0.001$ ) with a high prevalence of deviations in the TTA group. Deviations of knee kinematic measures at the prosthetic limb ranged in



**FIGURE 1.** Graphical representation of the NRR for selected measures using the AB group mean value ♦ and 2 SD bars. The value for each individual @ in the TTA group is plotted against the NRR for that measure. Five combinations of deviation prevalence level in the TTA group and significant group mean differences (\*) corresponding to values in Tables II and III are shown: (A) “High” prevalence (>50%) with a significant group mean difference, (B) Moderate prevalence (25–49%) with a significant group mean difference, (C) Moderate prevalence without a significant group mean difference, (D) Low prevalence (<25%) with a significant group mean difference, and (E) Low prevalence without a significant group mean difference

**TABLE II.** Peak Joint Angles, Moments, and Powers for the Lower Extremities and Trunk. Sagittal ROM and Temporal Spatial Measures are also presented. Values are Shown for the Right Limb of the AB Group and the Prosthetic and Intact Limbs of the TTA Group. Significant Group Differences between the Prosthetic and Intact Limbs and the Right Limb of the AB Group are Highlighted in Bold. For Each Peak Measure, the Timing of the Peak in the Gait Cycle is identified

Mean (SD)	AB	Prosthetic	Intact	Mean (SD)	AB	Prosthetic	Intact
Ankle Angle (°)				Ankle Moment (Nm/kg)			
Plantarflexion: LR	5.3 (3.0)	2.1 (3.6)	3.3 (2.7)	Dorsiflexion: LR	0.23 (0.07)	<b>0.31 (0.08)</b>	<b>0.28 (0.07)</b>
Dorsiflexion: TSt	14.1 (3.8)	16.3 (2.9)	14.1 (3.3)	Plantarflexion: TSt	1.38 (0.15)	1.28 (0.15)	1.38 (0.13)
Plantarflexion: ISw	14.9 (5.0)	<b>-4.7 (2.7)</b>	15.8 (6.4)	Ankle Powers (BW/kg)			
Sagittal ROM	29.0 (3.9)	<b>18.4 (3.2)</b>	30.2 (5.0)	Absorption: LR	0.26 (0.11)	0.28 (0.09)	<b>0.43 (0.18)</b>
				Absorption: TSt	0.77 (0.26)	0.94 (0.30)	0.87 (0.31)
				Generation: TSt	2.38 (0.51)	<b>1.39 (0.34)</b>	2.51 (0.58)
Knee Angle (°)				Knee Moment (Nm/kg)			
Flexion: IC	-5.7 (4.1)	-1.0 (6.3)	-5.8 (3.7)	Flexion: LR	0.41 (0.10)	<b>0.30 (0.07)</b>	<b>0.51 (0.07)</b>
Flexion: LR	10.9 (5.1)	7.8 (7.7)	9.2 (4.8)	Extension: MSt	0.46 (0.21)	<b>0.22 (0.18)</b>	0.39 (0.15)
Extension: TSt	0.3 (4.3)	2.5 (6.7)	-1.3 (3.2)	Flexion: TSt	0.34 (0.17)	0.20 (0.14)	0.40 (0.08)
Flexion: MSw	60.4 (4.4)	55.9 (6.7)	<b>55.5 (5.2)</b>	Extension - TSt	0.15 (0.07)	0.15 (0.06)	0.11 (0.03)
Sagittal ROM	68.9 (4.3)	<b>58.0 (8.7)</b>	<b>63.6 (5.5)</b>	Varus: LR	0.08 (0.05)	<b>0.01 (0.04)</b>	0.08 (0.06)
				Valgus: LR	0.41 (0.11)	0.32 (0.10)	0.44 (0.14)
				Knee Powers (BW/kg)			
				Generation: MSt	0.95 (0.29)	<b>0.24 (0.12)</b>	1.09 (0.39)
				Absorption: LR	0.57 (0.34)	<b>0.15 (0.18)</b>	0.45 (0.26)
				Generation: TSt	0.48 (0.23)	<b>0.22 (0.15)</b>	0.50 (0.15)
				Absorption: TSt	0.78 (0.32)	0.76 (0.18)	0.52 (0.19)
Hip Angle (°)				Hip Moment (Nm/kg)			
Flexion: LR	26.5 (5.5)	26.5 (6.7)	21.5 (6.0)	Extension: LR	0.82 (0.18)	<b>0.64 (0.09)</b>	<b>1.00 (0.14)</b>
Extension: PSw	9.4 (5.2)	13.1 (6.4)	15.0 (6.5)	Flexion: TSt	0.78 (0.20)	0.77 (0.21)	<b>0.60 (0.15)</b>
Flexion: TSw	29.6 (5.5)	27.9 (5.6)	<b>21.8 (6.3)</b>	Extension: Sw	0.30 (0.07)	0.37 (0.11)	<b>0.40 (0.07)</b>
Sagittal ROM	39.1 (3.0)	41.2 (3.8)	37.4 (1.9)	Abductor	0.76 (0.12)	0.74 (0.14)	0.89 (0.17)
Adduction	5.1 (2.4)	3.9 (2.6)	5.6 (2.1)	Adductor	-0.16 (0.06)	<b>-0.08 (0.03)</b>	-0.18 (0.06)
Abduction	8.1 (2.4)	6.0 (3.6)	<b>2.7 (2.9)</b>	Hip Powers (BW/kg)			
				Generation: MSt	0.44 (0.23)	<b>0.67 (0.13)</b>	0.51 (0.20)
				Absorption: TSt	0.57 (0.18)	0.58 (0.23)	0.44 (0.16)
				Generation: TSt	0.83 (0.20)	0.85 (0.22)	0.75 (0.16)
Pelvic Angle (°)				Trunk-Pelvic Angle (°)			
Anterior Tilt	10.1 (4.4)	<b>5.9 (5.9)</b>	<b>5.9 (5.9)</b>	Sagittal ROM	3.45 (0.85)	4.44 (1.41)	N/A
Posterior Tilt	-7.0 (4.2)	-2.0 (5.9)	-1.8 (6.0)	Frontal ROM	13.57 (3.49)	<b>8.97 (1.90)</b>	N/A
Sagittal ROM	3.1 (0.7)	<b>4.0 (0.9)</b>	<b>4.1 (1.0)</b>	Transverse ROM	13.43 (3.32)	10.60 (2.51)	N/A
Contralateral Drop	3.7 (1.5)	<b>1.0 (1.5)</b>	3.6 (1.6)	Trunk-Lab Angle (°)			
Contralateral Elevation	3.7 (2.1)	3.5 (1.6)	<b>1.0 (1.5)</b>	Sagittal ROM	3.52 (0.74)	<b>3.76 (0.57)</b>	N/A
Frontal ROM	7.4 (2.6)	<b>4.5 (1.0)</b>	<b>4.6 (1.1)</b>	Frontal ROM	5.27 (1.61)	6.99 (2.37)	N/A
Hip Forward	5.4 (2.8)	4.8 (2.7)	3.8 (2.8)	Transverse ROM	6.47 (1.98)	7.97 (2.02)	N/A
Hip Back	5.6 (2.8)	3.6 (3.0)	4.7 (2.8)				
Transverse ROM	10.9 (3.2)	8.4 (3.4)	8.6 (2.1)				
Temporal (s)				Spatial (m)			
Stance Time	0.73 (0.04)	0.71 (0.06)	0.75 (0.04)	Step Length	0.70 (0.05)	0.73 (0.16)	0.65 (0.10)
Swing Time	0.44 (0.03)	0.44 (0.03)	<b>0.41 (0.02)</b>	Step Width	0.12 (0.03)	0.13 (0.03)	0.12 (0.03)
Step Time	0.58 (0.03)	0.61 (0.13)	0.54 (0.08)	Stride Length	1.41 (0.09)	1.38 (0.11)	1.39 (0.09)

BW, body weight; ROM, range of motion; IC, initial contact; LR, loading response; MSt, midstance; TSt, terminal stance, St, stance; PSw, preswing; ISw, initial swing; MSw, midswing; TSw, terminal swing; Sw, swing. N/A: Trunk motion is tracked as 1 segment; therefore, duplicate measures in the intact limb are not reported. Kinematic and kinetic measures in bold exhibit a significant between group differences after Bonferroni-Holm correction with the smallest  $p$ -value cutoff of 0.0009. Temporal spatial measures in bold exhibit a significant between group differences after Bonferroni-Holm correction with the smallest  $p$ -value cutoff of 0.0083.

prevalence from 18.8 to 31.3% and were not significantly different from the AB group; with the exception of sagittal ROM (68.8% deviation prevalence,  $p \leq 0.001$ ). Each of the knee kinematic measures in the prosthetic limb, except ini-

tial contact flexion, had values that were both greater and less than the NRR, resulting in statistically similar means between groups. Six of 14 knee kinetic measures in the intact and prosthetic limbs were significantly different from



**TABLE III.** Prevalence (%) of Individuals within the TTA Group with Kinematic, Kinetic, or Temporal Spatial Deviations of the Prosthetic or Intact Limbs as Identified Using an AB NRR for Each Measure. “**High**” (>50%), **Moderate** (25–49%), and Low (<25%) Prevalence is Indicated for Each Measure. Arrows Represent a Significant Increase (↑) or Decrease (↓) in the TTA Mean Group Measure Relative to the AB Group and Correspond to Differences Presented in Table II. For Each Peak Kinematic and Kinetic Measure, the Timing of the Peak in the Gait Cycle is identified

Deviation Prevalence (%)	Prosthetic	Intact	Deviation Prevalence (%)	Prosthetic	Intact
Ankle Angle			Ankle Moment		
Plantarflexion: LR	18.8%	6.3%	Dorsiflexion: LR	↑ 12.5%	↑ 12.5%
Dorsiflexion: TSt	6.3%	0.0%	Plantarflexion: TSt	6.3%	0.0%
Plantarflexion: ISw	↓ <b>100.0%</b>	12.5%	Ankle Powers		
Sagittal ROM	↓ <b>81.3%</b>	6.3%	Absorption: LR	6.3%	↑ <b>43.8%</b>
			Absorption: TSt	12.5%	12.5%
			Generation: TSt	↓ <b>50.0%</b>	12.5%
Knee Angle			Knee Moment		
Flexion: IC	18.8%	6.3%	Flexion: LR	↓ 6.3%	↑ 6.3%
Flexion: LR	<b>25.0%</b>	6.3%	Extension: MSt	↓ 0.0%	0.0%
Extension: TSt	18.8%	0.0%	Flexion: TSt	12.5%	0.0%
Flexion: MSw	<b>31.3%</b>	↓ 12.5%	Extension: TSt	6.3%	0.0%
Sagittal ROM	↓ <b>68.8%</b>	↓ 18.8%	Varus: LR	↓ 18.8%	6.3%
			Valgus: LR	12.5%	12.5%
			Knee Powers		
			Generation: MSt	↓ <b>87.5%</b>	12.5%
			Absorption: LR	↓ 0.0%	0.0%
			Generation: TSt	↓ 0.0%	0.0%
			Absorption: TSt	0.0%	6.3%
Hip Angle			Hip Moment		
Flexion: LR	12.5%	18.8%	Extension: LR	↓ 0.0%	↑ 6.3%
Extension: PSw	18.8%	<b>31.3%</b>	Flexion: TSt	6.3%	↓ 6.3%
Flexion: TSw	12.5%	↓ <b>31.3%</b>	Extension: Sw	<b>31.3%</b>	↑ 18.8%
Sagittal ROM	18.8%	0.0%	Abductor	6.3%	<b>31.3%</b>
Adduction	12.5%	0.0%	Adductor	↓ 12.5%	0.0%
Abduction	<b>31.3%</b>	↓ <b>56.3%</b>	Hip Powers		
			Generation: MSt	↑ 0.0%	6.3%
			Absorption: TSt	12.5%	12.5%
			Generation: TSt	6.3%	6.3%
Pelvic Angle			Trunk-Pelvic Angle		
Anterior Tilt	↓ <b>31.3%</b>	↓ <b>31.3%</b>	Sagittal ROM	<b>37.5%</b>	N/A
Posterior Tilt	<b>31.3%</b>	<b>31.3%</b>	Frontal ROM	↓ 6.3%	N/A
Sagittal ROM	↑ <b>25.0%</b>	↑ <b>25.0%</b>	Transverse ROM	6.3%	N/A
Contralateral Drop	↓ <b>37.5%</b>	0.0%	Trunk-Lab Angle		
Contralateral Elevation	0.0%	↓ 12.5%	Sagittal ROM	0.0%	N/A
Frontal ROM	↓ 0.0%	↓ 0.0%	Frontal ROM	<b>25.0%</b>	N/A
Hip Forward	6.3%	0.0%	Transverse ROM	12.5%	N/A
Hip Back	0.0%	12.5%			
Transverse ROM	6.3%	0.0%			
Temporal			Spatial		
Stance Time	18.8%	6.3%	Step Length	<b>31.3%</b>	<b>43.8%</b>
Swing Time	6.3%	↓ <b>25.0%</b>	Step Width	0.0%	0.0%
Step Time	<b>31.3%</b>	<b>37.5%</b>	Stride Length	18.8%	12.5%

Significant between group differences of kinematic and kinetic measures are after Bonferroni–Holm correction with the smallest  $p$ -value cutoff of 0.0009. Significant between group differences of temporal spatial measures are after Bonferroni–Holm correction with the smallest  $p$ -value cutoff of 0.0083.

the AB group ( $p \leq 0.001$ ), but showed low deviation prevalence in the TTA group.

### Hip

The greatest prevalence of deviations at the hip of the intact limb was with abduction (56.3%). All sagittal plane

hip kinematic measures of the prosthetic limb had low deviation prevalence (12.5–18.8%), but unlike the knee of the prosthetic limb, the measures are skewed in a single direction relative to the NRR. Moderate deviation prevalence was observed for intact limb hip extension during preswing and flexion during terminal swing, however, only the latter

was found to be significantly different from the AB group ( $p \leq 0.001$ ).

### **Pelvis/Trunk**

Deviation prevalence was low to moderate for all pelvic and trunk measures of the TTA group. Five individuals (31.3%) with TTA accounted for all deviations of anterior and posterior tilt. Overall, the TTA group ambulated with less anterior pelvic tilt and had a significantly larger sagittal ROM than the AB group ( $p \leq 0.001$ ). In the AB group, the frontal plane motion was symmetrical, with 3.1 (SD 1.5) degrees of contralateral drop and 3.7 (SD 2.1) degrees of contralateral elevation relative to the stance limb. However, the TTA group demonstrated asymmetric pelvic motion with significantly reduced contralateral pelvic drop on the prosthetic limb and intact limb elevation ( $p \leq 0.001$ ). The frontal pelvic ROM of the TTA group was significantly decreased ( $p \leq 0.001$ ), although there were no values outside the NRR.

### **DISCUSSION**

The current study is the first, to our knowledge, to identify and characterize deviations in individuals with a TTA using both group mean comparisons and NRRs. The use of NRR and prevalence is presented as an additional method for identifying and quantifying deviations in individuals with a TTA likely to be encountered in a treatment environment. This approach allows direct comparisons of each individual to the NRR. This is in contrast to the group mean approach which, as evident in (Fig. 1), requires a high proportion of values be consistently greater or less than the AB group mean, or a few individuals with a TTA with large deviations in the same direction. When using the NRR approach, a relatively large sample of AB individuals is needed to provide an accurate estimate of NRRs. In this study, data from 40 AB males were the largest sample available at the time of analysis and presented in Table II for use by others.

### **Prosthetic Limb**

Similar to previous reports, individuals with a TTA in this study exhibited significant kinematic<sup>16</sup> and kinetic<sup>10,19</sup> deviations at the prosthetic ankle. Kinematic deviations such as decreased peak plantarflexion during initial swing and decreased sagittal ROM were highly prevalent. The decrease in peak plantarflexion was due to an inability of the prosthetic devices to actively plantarflex. When unloaded, these passive devices return to their aligned position of approximately 5 degrees of dorsiflexion. The use of passive prosthetic devices and associated decrease in plantarflexion contributed to the significant decrease in prosthetic ankle power generation at terminal stance. Similar to earlier works,<sup>10,19</sup> individuals with a TTA on average exhibited an approximate 50% reduction in prosthetic ankle power generation at terminal stance compared to the intact ankle

and AB group. However, this deviation was only prevalent in 50% of our TTA group. This suggests that, although prosthetic ankle ROM was limited, 50% of the TTA group were capable of achieving push-off powers within the NRR. This demonstrates that performance within normative ranges is possible, and interventions which allow individuals with a TTA to more effectively load and store energy in the foot are warranted.

Individuals with a TTA in the present study walked with a significant decrease in prosthetic limb sagittal knee ROM, which was highly prevalent and may be related to an extended knee posture observed in the prosthetic limb throughout gait. In agreement with previous reports, the effects of the extended knee posture were greatest at initial contact when individuals with a TTA displayed a significantly decreased knee flexor moment<sup>15,16</sup> and a significant and highly prevalent reduction in knee power generation.<sup>15</sup> Significant decreases in sagittal knee moments and powers measured later in stance were consistent with earlier works,<sup>11,15,16,19,27</sup> however, demonstrated 0% deviation prevalence meaning all values were within the NRR. These kinetic differences may be related to a compensatory extended knee posture, which prevents the knee from collapsing<sup>16</sup> during stance.

Similar to previous literature,<sup>12,16</sup> individuals with a TTA demonstrated a trend toward greater hip extension during prosthetic limb stance. This was associated with a significant increase in hip power generation during stance<sup>10,12,19</sup> and used to control knee flexion in the prosthetic limb and aid forward progression.<sup>19</sup> Despite significant kinetic group mean differences, the TTA group exhibited little to no prevalence of hip deviations. Longitudinal analysis of our participants would provide insight into when and if compensations at the hip develop.

### **Intact Limb**

Individuals with a TTA in the present study exhibited no significant differences in intact ankle kinematics compared to the AB group. However, a significant increase in intact ankle power absorption at initial contact was observed with 43.8% prevalence. We speculate this was in response to an abrupt transition off the prosthetic ankle at terminal stance and onto the intact limb at initial contact.<sup>28</sup> Individuals with a TTA must transition off the prosthetic foot more quickly due to a shortened roll-over arc of the prosthetic foot<sup>28</sup> and lack of active plantarflexion. This is consistent with the significant reduction in intact limb swing times observed in the TTA group. The increase in intact ankle power absorption during loading response may be associated with reports of increased intact limb loading<sup>1,3,5,29</sup> thought to contribute to secondary musculoskeletal disorders.

The results from the intact limb knee are in contrast to previous works, which reported increases in swing knee flexion,<sup>11</sup> maximum extension moments,<sup>11,16</sup> and stance knee

power generation.<sup>11,14</sup> The few significant kinematic and kinetic differences observed demonstrated prevalence less than 18.8%. Thus, it appears that knee deviations of the intact limb noted in older populations with a TTA<sup>11,14,16</sup> may not frequently occur in our young population with a TTA this early following independent ambulation.

In contrast to Bateni et al<sup>10</sup> who reported an increase in hip flexion of the intact limb during stance, we observed a trend toward increased extension throughout the gait cycle compared to the AB group. During swing, individuals with a TTA demonstrated significant decreases in hip flexion and abduction of the intact limb not previously reported in the literature. These deviations were 31.3% and 56.3% prevalent, respectively, and may be associated with the significant decrease in swing time and a rapid transition onto the intact limb. Consistent with these results, individuals with a TTA demonstrated a significant increase in swing hip extension moments at the intact limb, likely in preparation for initial contact with a shortened step length. However, most intact limb hip kinetic values were within the NRR with less than 32% prevalence. Similar to the intact limb ankle and knee, individuals with a TTA in this study did not frequently exhibit hip deviations reported in populations with a longer history of prosthetic ambulation.<sup>10,12,14</sup>

### **Pelvis/Trunk**

To the best of our knowledge, no study has reported pelvis and trunk biomechanical data for individuals with a TTA in all three planes of motion. Consistent with a previous report of asymmetry in pelvic obliquity,<sup>13</sup> our participants exhibited a significant decrease in pelvic drop on the intact side with 37.5% prevalence. Although we found significantly decreased frontal plane pelvic ROM using group comparisons, all individual values were within the NRR. The 0% deviation prevalence is consistent with the work of Rueda et al<sup>30</sup> suggesting no difference between TTA and AB groups. In addition to the frontal plane deviations, individuals with a TTA exhibited a significant decrease in anterior pelvic tilt compared to the AB group with 31.5% prevalence. The presence of pelvic and trunk deviations early following independent ambulation and their potential links to the development of low back pain<sup>13,31</sup> suggest longitudinal study of pelvic and trunk deviations and their relationship to low back pain may be warranted.

### **CONCLUSION**

Prosthetic limb deviations identified and characterized using group mean and prevalence approaches are in general agreement with, and add to, those reported in the literature. Specifically, knee and hip deviations observed in the prosthetic limb are indicative of known compensations used to control the knee during stance. Decreased prosthetic ankle power generation during push off did not, however, appear to elicit compensations in the intact limb, knee, and hip. Further,

individuals with a TTA in this study exhibited few of the intact limb deviations that have been previously reported. Inconsistencies between our data and previous literature may be associated with differences in age, activity level, or prosthetic gait experience. Prior data demonstrating recovery of normative metabolic cost of walking and greater function in the injured service member as compared to civilian cohorts are consistent with the reduced deviations observed here.<sup>32</sup> Finally, pelvic and trunk deviations in all three planes of motion are reported here for the first time. The use of the NRR method allows clinicians and researchers to identify gait deviations in a single individual matching clinical practice. Further study is needed to determine the exact etiology of these deviations, and their association with the development of secondary musculoskeletal conditions.

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# A Narrative Review of the Prevalence and Risk Factors Associated With Development of Knee Osteoarthritis After Traumatic Unilateral Lower Limb Amputation

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**ABSTRACT** Introduction: Young military Service Members with traumatic unilateral lower limb amputations may be at a high risk for developing knee osteoarthritis (OA). There is growing evidence for potential influence and predictive value of nonsystemic risk factors on development and progression of primary knee OA in older adults. Proposed factors include chronic knee pain, obesity, abnormal knee joint mechanics, muscle weakness, previous knee trauma, and altered physical activity level. However, there is limited information available regarding whether such nonsystemic risk factors could also be responsible for the increased risk of knee OA after traumatic, unilateral lower limb amputation in young military Service Members. The purpose of this narrative review is to compile and present evidence regarding prevalence of nonsystemic and potentially modifiable knee OA risk factors in Service Members with traumatic, unilateral lower limb amputation, and to identify potential strategies for intervention. Materials and Methods: A comprehensive literature search was performed in July 2015 using structured search terms related to nonsystemic risk factors for knee OA. Results: Current collective evidence does suggest an elevated prevalence of the nonsystemic knee OA risk factors in young military Service Members with unilateral lower limb amputation. In conclusion, the present state of the literature supports that young military Service Members with traumatic unilateral lower limb amputations may be at increased risk for developing knee OA compared to nonamputees. Military Service Members injured at a young age have a long life expectancy, and thus require comprehensive rehabilitation programs to prevent or delay progression of knee OA. Given the lack of strong evidence, further clinical research is needed to determine whether early identification and modification of nonsystemic risk factors for knee OA could optimize long-term function and quality of life in young Service Members after traumatic, unilateral, limb amputations.

## BACKGROUND

Young military Service Members who have sustained an amputation have unique long-term health care and rehabilitation needs. Traumatic limb amputations, in particular, represent an important source of chronic impairments and functional limitations that could significantly impact returning to active duty, employment status and long-term quality of life (QOL) in young military Service Members. Although a significant amount of resources have been focused on the immediate rehabilitation needs of young Service Members after amputation, an important consideration is the early identification and modification of potential risk factors responsible for long-term development of secondary health conditions such as knee osteoarthritis (OA).

## KNEE OA AFTER TRAUMATIC UNILATERAL LOWER LIMB AMPUTATION

Individuals with traumatic, unilateral lower limb amputation are at a greater risk of developing knee OA compared to

nonamputees. Melzer et al reported that the prevalence of contralateral knee OA was 66% in 32 individuals with lower limb amputation, which was significantly greater than a 38% prevalence rate detected in an age- and body weight-matched control group consisting of 24 individuals without an amputation.<sup>1</sup> Similarly, Hungerford and Cockin<sup>2</sup> reported knee OA prevalence rates of 63%, 41%, and 21% in transfemoral amputees, transtibial amputees, and matched controls, respectively. Conversely, Norvel et al<sup>3</sup> reported that the prevalence of symptomatic knee OA was 16% among 62 older amputees with no history of previous knee trauma as compared to an 11% rate in 94 elderly nonamputees. Exclusion of previous knee trauma, which is a strong risk factor for knee OA, could be partially responsible for the reports of lower contralateral knee OA by Norvel et al.<sup>3</sup> More recently, Struyf et al<sup>4</sup> reported knee OA prevalence rates of 27% for the intact limbs of 78 individuals with traumatic, unilateral lower limb amputation (mean age 60 years) that were considerably higher than the age- and gender-adjusted rates in the general population. The much lower knee OA prevalence rates after traumatic, unilateral limb amputation in this study compared to previous publications may be associated with advancements in prosthetic design and rehabilitation of individuals with lower limb amputation over the past decade. Nevertheless, the current evidence suggests that the intact limbs of individuals with traumatic, unilateral lower limb amputation are at great risk for developing knee OA. Given

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the importance of the intact limb for preservation of mobility and functional independence in individuals with unilateral lower limb amputation, risk factor identification, and early disease detection appear to be of high importance for effective prevention and rehabilitation of knee OA in this patient population.

### **KNEE OA PATHOMECHANICS AND RISK FACTORS**

The knee is one of the joints most commonly affected by OA with a 50% lifetime risk of developing symptomatic disease in the general population.<sup>5</sup> As there is no cure, conservative management of knee OA has traditionally focused on pain management and improving overall mobility. However, due to the degenerative nature of the disease, knee OA commonly progresses to a stage where joint replacement surgery may be the only viable option for alleviating symptoms and improving function and QOL. However, joint replacement surgery may not be a feasible option for some patients such as those with lower limb amputation or other concomitant comorbidities. Therefore, attempts are currently underway to identify potentially modifiable risk factors and implement joint protective strategies that can result in favorable long-term outcomes.

Although knee OA has long been viewed as a non-inflammatory “wear and tear” of the articular cartilage in older adults, this disease paradigm is rapidly changing. There is now mounting evidence that although OA is a mechanically driven condition, the disease process is chemically mediated through a complex interplay between systemic and nonsystemic factors.<sup>6,7</sup> Normal articular cartilage has a unique load-bearing mechanism capable of tolerating customary daily loads without sustaining injury that is determined through contributions from genetics,<sup>8</sup> as well as mechanical<sup>9</sup> and age-related factors.<sup>10</sup> However, long-term exposure to excessive loads and other changes in joint mechanics, similar to those observed after lower limb amputation,<sup>11–14</sup> can lead to adaptive cellular responses and altered gene expressions that facilitate the onset and progression of the disease.<sup>7,15</sup>

Although systemic risk factors such as genetic predisposition<sup>16</sup> may increase the risk of knee OA development after traumatic limb amputation through gene-specific and time-dependent alterations in gene expression, e.g., these factors are permanent and nonmodifiable, which makes them unlikely as direct preventative or therapeutic targets. Conversely, previously identified nonsystemic and potentially modifiable risk factors such as chronic knee pain,<sup>17,18</sup> obesity,<sup>19,20</sup> abnormal knee joint mechanics,<sup>6,7</sup> lower limb muscle weakness,<sup>6,21</sup> previous joint trauma,<sup>22</sup> and altered physical activity levels<sup>23,24</sup> are all modifiable through preventative and rehabilitative strategies that could be applied to individuals with lower limb amputation. Therefore, the purpose of this narrative review is to organize the pertinent literature in an effort to identify nonsystemic, potentially modifiable risk factors related to the development and progression of knee OA in the sound limbs

of Service Members with traumatic amputations and identify possible prevention and treatment solutions.

### **REVIEW CRITERIA**

Electronic searches of PubMed and EMBASE databases were performed in July 2015. MeSH terms for the initial search included “knee,” “OA,” “amputation,” and “trauma.” A comprehensive search was performed for each nonsystemic, OA-related risk factor by combining the initial search strategy with the combination of the following keyword search terms: “pain,” “obesity or body mass index or BMI,” “biomechanics or load or force or moment or rate,” “muscle and (weakness or strength or symmetry),” “acute joint injury or trauma,” and “physical activity or sports participation.” All titles and abstracts were screened for content and pertinence to the purpose of the review. In cases where direct evidence was lacking, additional supplemental manual searches were performed for relevant articles based on reference lists of the retrieved articles or relevant published literature related to knee OA and its risk factors in the general population.

### **CHRONIC KNEE PAIN**

Presence of chronic knee pain has been deemed as an early indicator of degenerative joint changes that may appear before evidence of radiographic knee OA in nonamputees.<sup>17</sup> The commonly used conventional radiographs are known to be insensitive to detecting early OA structural changes and are often only useful in measuring late-stage disease.<sup>25</sup> More recently it has been suggested that symptoms often precede the appearance of radiographic abnormalities, implying the existence of a potentially detectable “prodromal phase” in the transition from preradiographic to radiographic stages of OA.<sup>18</sup> As such, knee pain with activities associated with higher dynamic knee loading such as climbing stairs has been suggested to help identify individuals with preclinical knee OA suitable for early intervention strategies.<sup>17,18</sup> Furthermore, presence of chronic knee pain has been identified as an early sign of future OA-related risk of functional decline.<sup>26</sup>

After lower limb amputation, high knee pain prevalence rates of 50 to 55% and 36 to 38% have been reported in the intact limbs of individuals with unilateral transfemoral and transtibial amputations, respectively, compared to only a 20% prevalence rate among nonamputees.<sup>3,27,28</sup> Conversely, the residual knee on the side of a transtibial amputation has been reported to be five times less likely to be painful compared to matched knees in nonamputees.<sup>3</sup> Furthermore, Burke et al<sup>29</sup> reported a knee pain prevalence rate of 52% in the intact limbs of individuals with unilateral transtibial amputations as compared to no reports of pain in the residual side knee. The higher prevalence of knee pain on the side of the intact lower limb in individuals with unilateral amputation is consistent with the patterns of knee OA reported in this patient population and may be a sign of

underlying disease that could be used for initiation of early prevention and intervention strategies.

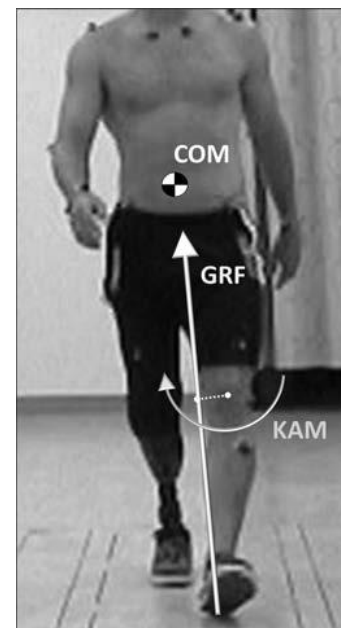
## OBESITY

Obesity is a well-documented individual risk factor for primary knee OA in older adults. To this end, a three-fold increase in risk of future knee OA development has been previously reported for young men between the ages of 20 and 29 years with BMI values between 24.7 and 37.6 kg/m<sup>2</sup> compared to their leaner counterparts with BMI values between 15.6 and 22.8 kg/m<sup>2</sup>.<sup>19</sup> Epidemiologic studies have previously demonstrated that obesity is linked to both the development and progression of knee OA<sup>20</sup>; however, there is considerable debate about how obesity contributes to the onset and progression of the disease. Potential mechanisms for the contribution of obesity to knee OA include (1) a generalized negative metabolic environment reflecting a systemic inflammatory response to the products secreted by the adipose tissues;<sup>30,31</sup> (2) increased cumulative compressive loads experienced by the joint due to a greater body mass;<sup>32</sup> or (3) a combination of both metabolic and biomechanical factors. Currently, evidence in support of the metabolic explanation of the link between obesity and knee OA are mixed. Although some authors have suggested that metabolic factors associated with obesity contribute to the pathogenesis of knee OA,<sup>30,31</sup> others have not supported this premise.<sup>33</sup> On the other hand, the biomechanical theory explaining the potential link between knee OA and obesity is well supported by the contention that excessive body mass increases the loads placed on the knee joint.<sup>32</sup> For example, it has been reported that a weight increase of 1 kg can result in a four-fold (4 kg) increase in compressive knee joint loads per step during activities of daily living.<sup>32</sup> However, the potentially deleterious effects of greater joint loads due to an increase in body mass may be countered by the lower activity level, slower preferred walking speed, and less number of steps taken per day by individuals with higher body mass, therefore reducing the total knee joint loading exposure.

Clinical observations suggest that individuals with traumatic lower limb amputation are at increased risk for weight gain and obesity. Kurdibaylo<sup>34</sup> reported higher fat content in body mass for individuals with transtibial (21%) and transfemoral amputations (23%) compared to age-matched controls (13%). Norvell et al<sup>3</sup> also reported significantly higher average body weight and BMI for individuals with unilateral transtibial and transfemoral amputations compared to control subjects greater than 40 years of age. Younger individuals with amputations, in particular, are at high risk of obesity progression within their first year status post amputation, mostly as a result of a sedentary lifestyle immediately after amputation but before prosthesis fitting.<sup>34</sup> Given that military standards for recruitment commonly exclude overweight volunteers, increased risk of obesity after lower limb amputation is most likely a consequence of the limb loss, which provides a great opportunity for initiation of early weight management strategies.

## ABNORMAL KNEE JOINT MECHANICS

Knee joint mechanics experienced over time create a customary joint loading history that helps to precondition the tissue to withstand repeated mechanical demands without sustaining injury.<sup>35</sup> However, joint damage may occur when the mechanical environment is significantly altered, such that new patterns of cartilage stresses/strains outside a habituated envelope result.<sup>35</sup> This may be a concern after a traumatic, unilateral lower limb amputation, where the intact limb is challenged by increased demands for body support and forward progression. Several key reviews within the past decade have summarized the specific mechanical factors which influence the onset and progression of compartment knee OA in the general population<sup>9,36,37</sup> and after lower limb amputations.<sup>38,39</sup> In both populations, the external knee adduction moment (KAM) has been the most frequently used surrogate measure for medial knee joint loading related to knee OA. The KAM may be roughly estimated by multiplying the magnitude of the ground reaction force (GRF) in the frontal plane with the lever arm distance between the line of action of the GRF and the knee joint axis of rotation (Fig. 1). Individuals with knee OA characteristically demonstrate elevated peak KAM during walking that are strongly associated with severity of medial compartment knee OA, which is 10 times more prevalent in the general nonamputee population than lateral compartment knee OA.<sup>9,36</sup> Furthermore, for patients with existing medial knee OA, KAM magnitude at baseline has strong associations with baseline knee pain severity, and was shown to be longitudinally



**FIGURE 1.** Schematic representation of intact limb knee adduction moment (KAM) during initial limb loading. Ground reaction force (GRF) magnitude, along with the perpendicular distance (white dotted line) between the GRF line of action and the frontal plane knee center of rotation approximates KAM magnitude, which is highly determinate of compressive load within the medial knee compartment.



predictive of OA radiographic progression.<sup>40</sup> However, measures useful in predicting progression of existing OA may differ from those associated with initiation of OA.<sup>40</sup>

Previous investigations of walking in individuals with transtibial amputations (mean age ranging 41.2–56.3 years old) have reported 33 to 56% greater peak KAM on the intact limb than on the prosthetic limb, depending on walking speed and the type of prosthetic foot used in the study.<sup>13,41–44</sup> While this is greater relative to an asymmetry of ~10% in non-amputees,<sup>45</sup> the intact limb may not necessarily be overloaded in direct comparison to the limb of a speed-matched non-amputee. For example, Royer et al<sup>44</sup> found a 56% greater peak KAM on the intact limb relative to the prosthetic side in individuals with unilateral transtibial amputations, associated with a 45% greater tibial plateau bone mineral density on the intact limb, relative to the prosthetic side. However, neither peak KAM magnitude nor the bone mineral density for the intact limb were significantly different from speed- and age-matched nonamputees.<sup>44</sup> In contrast, a number of other studies have instead found mechanical differences in the sagittal plane, reporting 48% greater peak external knee extension moments on the intact limb, relative to the prosthetic side.<sup>12–14</sup>

Higher-level analysis of net GRFs can also lend insight into pathomechanics of knee OA in individuals with limb amputation. In general, findings from collected literature support net overloading of the intact side relative to the prosthetic side, as well as relative to speed-matched nonamputees. For example, persons with unilateral transtibial amputation have a greater intact-limb peak vertical GRF during loading response relative to nonamputees, by as much as 4 to 10% during walking<sup>46,47</sup> and 35 to 45% during running.<sup>48</sup> Knee flexion angle and external knee extension moments, which are associated with GRF overloading and elevated axial knee joint compression,<sup>49</sup> have also been found greater in the intact limb of individuals with unilateral lower limb amputations compared to nonamputees.<sup>14,47</sup> Such net GRF differences may or may not lead to differences at each of the proximal joints, depending on concurrent kinematics and muscle activity. One study accounting for the latter factors found 23% greater peaks in axial knee joint total compression force on the intact limb relative to the prosthetic side, and 9% greater relative to nonamputee limbs.<sup>11</sup>

Prosthetic device mechanical properties have also proven to have a significant effect on mechanics of the proximal intact limb. Briefly, findings indicate that prosthetic foot stiffness and energy return properties can effect intact limb early stance GRFs, with as much as a 7% of body weight increase in peak vertical GRF when using a solid ankle cushion heel foot versus an energy storage and return foot.<sup>50,51</sup> Energy storage and return feet can also reduce intact limb peak KAM by as much as 13% versus a solid ankle cushion heel foot,<sup>41</sup> while an active prosthetic foot that provides timed, active propulsion near prosthetic limb push-off can decrease the magnitude of intact limb peak KAM by as much as 26%.<sup>43</sup> Currently, there is a clear need to ascertain whether such

prosthetic advancements are associated with a reduced incidence of knee joint pain and early OA in the intact limb of patients with unilateral amputation.

## **MUSCLE WEAKNESS**

Lower limb muscle weakness is a hallmark impairment for primary knee OA in older adults. In general, muscular strength is critical for maintaining proper dynamic joint function as muscles aid in shock absorption and proper force transfer across the joint.<sup>52</sup> To this end, quadriceps muscle weakness has been suggested as a strong risk factor for primary knee OA.<sup>6</sup> Several mechanical theories have been previously suggested for the potential relationship between quadriceps muscle weakness and structural knee OA development and progression. For instance, it has been suggested that quadriceps muscle plays a joint protective role as a shock absorber to dampen the rate of knee loading such as decreasing the heel strike transient during the loading response phase of gait.<sup>53</sup> In individuals with lower limb amputation, prior studies have shown a significant decrease in quadriceps strength for the prosthetic limb when compared to the intact limb.<sup>45,54</sup> Quadriceps atrophy has also been noted on the prosthetic side in comparison to the intact limb.<sup>55</sup> Comparisons of individuals with unilateral transtibial amputations to a control group have also demonstrated that those with amputations have weaker quadriceps bilaterally compared to nonamputees, which were highly correlated with increased rates of vertical impact loading of the lower limb during gait.<sup>45,54</sup>

While the quadriceps remain the major focus of research efforts examining the role of muscle weakness in pathogenesis of primary knee OA, a new body of evidence is emerging to suggest that hip muscle weakness may also be a risk factor for knee OA.<sup>56,57</sup> As the hip shares a common segment (i.e., the femur) with the knee, adequate hip muscle performance is necessary to provide dynamic proximal stability for maintaining appropriate knee joint mechanics during weight bearing.<sup>58</sup> For example, Chang et al<sup>56</sup> reported that a greater hip abductor strength is associated with a reduced likelihood of medial compartment knee OA progression. Other studies, however, have shown that strengthening of the hip musculature can lead to significant improvements in pain and function despite virtually no change in KAM in older adults with primary knee OA.<sup>59,60</sup> Strength testing in individuals with unilateral transfemoral amputations, traumatic and nontraumatic, has shown that isometric hip abduction strength of the amputated limb is 47 to 54% lower compared to the intact limb and 35 to 65% lower compared to nonamputees.<sup>61,62</sup> Conversely, Nadollek et al<sup>63</sup> found no difference in elderly individuals with unilateral transtibial amputations between the prosthetic and intact limbs; however, comparisons to hip strength in a control group were not made. Additional research is needed to provide a clearer picture of the prevalence and extent of lower limb muscle weakness and its potential relationship with development and progression of knee OA after traumatic lower limb amputation.

## **PREVIOUS KNEE INJURY OR TRAUMA**

High-impact loading knee injuries such as tears of the meniscus, ligaments, or capsule; joint dislocations; and intra-articular fractures in young individuals has been previously linked with a 5.2-fold increased relative risk of developing subsequent knee OA.<sup>22</sup> The energy initially absorbed by the joint surfaces at the time of injury has been suggested as an important predictor of development of knee post-traumatic OA (PTOA).<sup>64</sup> This PTOA has fundamentally different etiology than the primary degenerative OA discussed previously in this review. The emerging hypothesis related to PTOA is that the severity of the initial trauma and the subsequent cascade of pathophysiological events such as inflammation and chondrocyte senescence, along with any residual joint instability, incongruity, or alteration in biomechanics, contribute substantially to the onset and progression of knee OA.<sup>65</sup>

The risk of knee PTOA is most likely even higher in young military Service Members due to the high-energy nature of most battlefield injuries. In fact, in a recent report in combat-injured warriors who could not return to duty, injuries to the knee resulted in post-traumatic knee OA in every case at an average of  $19 \pm 10$  months after injury.<sup>66</sup> This trajectory of knee PTOA development after combat injuries appears to be much steeper than the 10 to 15 year rate previously reported after anterior cruciate ligament ruptures or meniscal damage in the general population.<sup>67–69</sup> Given that most combat-related injuries resulting from high-energy explosions involve multiple limbs and joints,<sup>66</sup> it is likely that the concurrent injury to the knee of the intact limb along with altered joint biomechanics after amputation could lead to a greater risk of developing PTOA in individuals with traumatic unilateral lower limb amputation. Additional research to better understand the involvement of multiple joint tissues and the critical cellular and molecular events after trauma and injury is needed to develop strategies (e.g., surgical, pharmaceutical, rehabilitative, etc.) to slow or halt the onset or progression of knee PTOA after lower limb amputation.

## **PHYSICAL ACTIVITY LEVEL**

Previous findings concerning the association between exercise, sports participation, and risk of knee OA have been somewhat perplexing. For instance, regular exercise has been suggested as a favorable option for maintaining articular cartilage health.<sup>35</sup> Experimental studies in animals have also shown that loading of healthy joints through moderate bouts of running is associated with increased articular cartilage thickness, proteoglycan content, and mechanical stiffness of the tissue.<sup>23,24</sup> In addition, recreational- or even elite-athlete level long-distance running have shown to be unrelated to accelerated incidence or severity of radiographic knee OA in the absence of underlying joint disease.<sup>70,71</sup> In contrast, other studies have associated participation in specific sports that involve running, jumping, and heavy lifting

with higher incidents of knee OA and an increased rate of disease progression.<sup>72,73</sup>

In general, individuals with unilateral transtibial amputation, regardless of traumatic or nontraumatic origin of the initial injury, demonstrate decreased activity levels when compared to nonamputees.<sup>74</sup> In previous literature, it has been reported that individuals with lower limb amputation on average take 1,540 to 3,163 steps per day,<sup>75,76</sup> as compared to healthy adults who ambulate anywhere between 4,000 and 18,000 steps per day.<sup>77</sup> Given that mechanical loading of the knee joint is inherently linked to maintenance of the articular cartilage, adequate levels of mechanical stimulation are essential for maintaining articular cartilage tissue homeostasis through balancing solid matrix synthesis and degeneration.<sup>78</sup> Therefore, lower frequency of knee joint loading due to diminished activity levels can lead to the reduction in cartilage tissue resiliency<sup>35</sup> needed to meet the requirements of higher demanding activities, such as sports participation or returning to active duty that may be desired by young Service Members with lower limb amputations.

It has been suggested that individuals with amputations who participate in sports and/or regular physical activity report significant benefits both physically and psychologically, such as improved strength, endurance, balance, and improved self-esteem and QOL.<sup>79</sup> Previous studies have shown that 32 to 60% of individuals with lower limb amputation participate in some form of sports, whether recreationally or competitively.<sup>80</sup> Currently, whether sports participation in individuals with lower limb amputation could be a risk factor for onset and progression of knee OA remains unknown. In a small study, Melzer et al<sup>1</sup> found no differences in the intact limb knee OA incidence between individuals with amputations who did and did not play volleyball. Additional longitudinal data are needed to better understand how early return to high-demanding sports activities may contribute to the onset and progression of knee OA. Additionally, Service Members are anticipated to perform physical activities beyond level walking and running, which warrants further investigation of such activities.

## **CONCLUSIONS**

Available scientific evidence to date supports that young military Service Members with traumatic, unilateral lower limb amputations may be at increased risk for developing knee OA compared to nonamputees. Given the high life expectancy of young injured military Service Members, development of effective rehabilitative programs to prevent or delay knee OA through early risk factor identification and modification is a crucial step in optimizing long-term function and QOL after traumatic, unilateral limb amputations. Future development of such programs should span a comprehensive range. Components should include screening of the intact limb for prior high-energy trauma and joint pain, managing body weight, further study of intact side knee joint mechanics, and

addressing lower limb muscle weakness. In retraining undesirable biomechanics, technological advancements to guide real-time feedback and adjustments in movement strategies may be useful.<sup>81,82</sup> Continued future research and clinical programs that address nonsystemic knee OA risk factors are anticipated to increase long-term preservation of intact limb function and overall QOL in young Service Members after unilateral lower limb amputation.

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# Differences in Military Obstacle Course Performance Between Three Energy-Storing and Shock-Adapting Prosthetic Feet in High-Functioning Transtibial Amputees: A Double-Blind, Randomized Control Trial

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**ABSTRACT** Background: Approximately 683 persons engaged in military service experienced transtibial amputation (TTA) related to recent war in Iraq and Afghanistan. Military TTAs function at a level beyond basic ambulation. No empirical data demonstrate which higher functioning prosthetic feet maximize injured service personnel's ability to continue performing at a level commensurate with return to duty. This study's purpose was to determine which of three high-functioning, energy-storing prosthetic feet maximize performance and preference in a field obstacle course (OC) and to quantify physical performance differences between TTAs and high-functioning nonamputees. Procedures: A randomized, double-blind, repeated measures experimental design compared three prosthetic feet (Ossur Variflex, Endolite Elite Blade, and Ossur Re-Flex Rotate) during performance on a field OC. TTAs accommodated with study feet and the OC before assessment. 14 TTAs and 14 nonamputee controls completed the course. Subjective and objective performance differences were compared across feet conditions and between groups. Results: Total OC completion times were similar between prosthetic feet: Elite-Blade (419 seconds  $\pm$  130), Variflex (425 seconds  $\pm$  144), and Re-Flex Rotate (444 seconds  $\pm$  220). Controls' OC completion time (287.2 seconds  $\pm$  58) was less ( $p \leq 0.05$ ) than TTA times. In total, controls had faster completion times ( $p \leq 0.05$ ) compared to all prosthetic feet conditions in 13/17 obstacles. Re-Flex Rotate had 2 additional obstacles different ( $p \leq 0.05$ ) than controls and required more time to complete. Median RPE values were lower ( $p \leq 0.05$ ) for controls than TTA regardless of foot. Regarding foot preference for OC completion, 7/14 (50%) preferred Elite Blade, 5/14 (36%) preferred Re-Flex Rotate, and the remaining 2/14 (14%) preferred Variflex. Conclusion: Controls completed the OC faster and with less effort than TTAs regardless of prosthetic foot. No clear differences in prosthetic feet emerged during OC completion; however, individual task performance, perceived effort, and preference resulted in trends of slight performance improvement with and preference for Elite Blade, a dual function energy-storing and return foot combined with vertical shock absorption. Understanding how to maximally improve performance in such functional tasks may allow service members to best sustain physical fitness, return to their military occupational specialty and possibly in-theater duty.

## INTRODUCTION

Traumatic amputation represents more than 2% of all battle-field injuries and greater than 7% of major extremity injury associated with military service.<sup>1,2</sup> Specific to the wars in

Iraq and Afghanistan, there have been 1,221 persons engaged in military service who have experienced 1,631 amputations from 2001 to 2011.<sup>3</sup> Of these, 683 amputations (or 41.8%) were at the transtibial level and 366 people suffered multiple amputations.<sup>1-4</sup> Military transtibial amputation (TTAs) likely function at a level beyond basic ambulation and will require a longer duration of care over their remaining lifespan compared to dysvascular amputees in the civilian sector. Today's younger military TTA will challenge the health care system that is best suited for management of lower functioning patients.<sup>5,6</sup>

Rehabilitation following TTA routinely involves use of a prosthesis. Optimizing the TTA prosthesis requires selecting componentry, including a prosthetic foot best suited for the patient's particular functional demands. Problematically, little empirical data are available to guide selection of the optimal foot for a high-functioning member of the armed forces who may be interested in extreme recreational pursuits as a Veteran or in staying on active military duty. Available comparative effectiveness research for prosthetic feet in the TTA population has included perceptible, biomechanical, and

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bioenergetic measures in a limited selection of prosthetic feet including solid ankle cushioned heel (SACH), energy-storing, and vertical shock-absorbing feet.<sup>7</sup> Briefly, compared to alternatives such as SACH feet, TTA's studied preferred energy-storing feet and reported enhanced performance, comfort and less effort in association with their use.<sup>7-12</sup> In some cases, additional functions have resulted in improved performance of specific functional needs. Examples include specialty running feet improving bioenergetic efficiency during ambulation above comfortable walking speeds and vertical shock absorption improving stair-climbing kinetics.<sup>13,14</sup> Despite the available, however limited evidence, there is no empirical data to demonstrate which higher functioning prosthetic feet can maximize an injured service member's ability to continue performing at a level commensurate with return to duty.

Obstacle courses (OCs) are a familiar element of military and law enforcement culture and qualification. They are used in preparatory training and skill maintenance in physically demanding work environments. OCs are further used for assessment to demonstrate continued preparedness in terms of skill proficiency and fitness. Use of OCs have become even more widespread to include recreation and to determine disease severity. In the health care literature for instance, OCs have been used with the elderly, those using assistive mobility aids, visually impaired, community ambulatory transfemoral amputees, those recovering from cardiac events, firefighters, and the military.<sup>15-24</sup> Use of OCs in these examples have provided determinations of fitness and situational preparedness for physically rigorous work environments. Given that OCs are familiar to military personnel to assess physical preparedness and because there are no field-based physical performance assessments of high-functioning TTAs using high-functioning prosthetic feet, use of an OC is a logical assessment choice in this population. Therefore, the purpose of this study was to determine which of three high-functioning, energy-storing prosthetic feet maximize performance and preference in a rigorous field OC. A second purpose was to quantify the differences in physical performance between persons with TTA and a high-functioning nonamputee control group.

## METHODS

The protocol was approved by Institutional Review Boards for the University of South Florida and the U.S. Army. The study was also listed in a federal clinical trials registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov); no. NCT01404559).

### Study Design

A randomized, double-blind (subjects and data collectors), repeated measures experimental design was used to compare three prosthetic feet conditions in physical performance. The study statistician (also blinded to the interventions) used an electronically generated, randomized, and balanced block allocation to sequence independent variable (prosthetic foot) assignment to subjects (off-site and concealed) via the study

prosthetists. The study prosthetists fabricated prosthetic blinding covers that concealed the identity of prosthetic feet during testing to mask participants and investigators.

### Subject Recruitment and Eligibility

TTA subjects were recruited in collaboration with case managers through a military treatment facility specializing in amputee rehabilitation as well as advertisement with local prosthetic and rehabilitative clinics. Nonamputee control subjects were recruited through the local County Sheriff Department's Special Weapons and Tactics Team (SWAT). All subjects had to be aged  $\leq 45$  years and provide evidence of medical clearance to be able to participate in vigorous physical activity. Nonamputee control subjects had to be a SWAT team member. Additional eligibility criteria specific to TTAs included that candidates had to be determined by study prosthetists to be at the K4 functional level and currently active duty military or other uniformed service, a recently separated Veteran or have a strong high-performance athletic history as an amputee (e.g., ranked triathlete, paralympian).

### Experimental Procedures

#### Study Feet (Independent Variables)

All amputee subjects (experimental group) were tested in random order with each of the following three energy-storing prosthetic feet (blinded) (Fig. 1).

- (1) Variflex (Ossur, Reykjavik, Iceland. Energy-storing and return [ESR]),
- (2) Elite Blade (Endolite, Hampshire, United Kingdom. Energy-storing and vertical shock absorption),
- (3) Re-Flex Rotate (Ossur, Reykjavik, Iceland. Energy-storing and vertical shock and torsion absorption).

These feet were selected as they represent differing types of energy-storing feet including a basic energy-storing foot, a light weight ESR foot with vertical shock absorption and a heavier ESR foot with vertical shock and torsion absorption. A cross-section of nonamputees were also assessed to provide a comparison to unimpaired physical performance (control group).

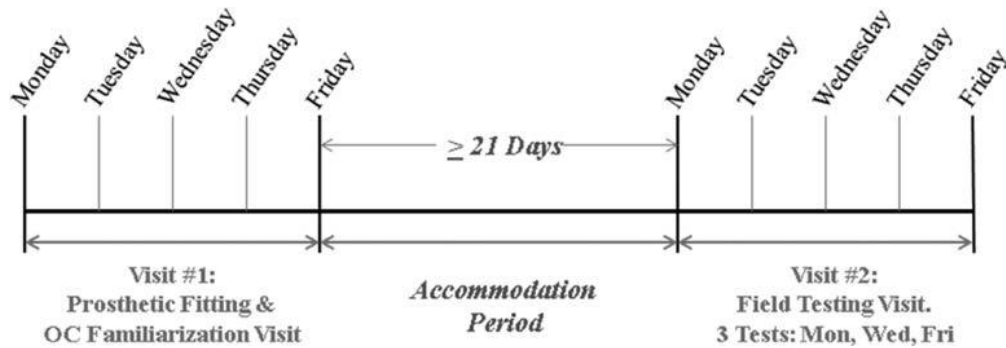
#### Prosthetic Fitting and Accommodation Periods

Board-certified and state-licensed study prosthetists duplicated TTA participants' prosthetic sockets and suspension. The duplicate socket was then fit and aligned (to manufacturer specifications using a LASAR posture tool [Otto Bock Healthcare, Duderstadt, Germany]) with the three 3 prosthetic feet using modular coupling components to control potential confounding issues related to socket fit. TTA participants accommodated with each prosthetic foot by wearing it for a minimum of 7 days (minimum of 8 hours per day). Participants recorded their foot accommodation use in a written journal provided to them during fitting and training. Usage





**FIGURE 1.** I. Variflex (Ossur, Reykjavik, Iceland) is an energy storing and return foot, II. Elite Blade (Endolite, Hampshire, United Kingdom) is an energy-storing and vertical shock absorption foot, III. Re-Flex Rotate (Ossur, Reykjavik, Iceland) is an energy-storing and vertical shock and torsion absorption foot.



**FIGURE 2.** Study timeline. The timeline included two 5-day research activity periods on either side of a 21-day accommodation period. The first 5-day period was for prosthetic fitting and OC training. The second 5-day period included 3 OC test sessions and 3 laboratory evaluation sessions (reported elsewhere). The 21-day accommodation period allowed for 7-day accommodation for each of the 3 study feet.

and minimal accommodation were confirmed by study staff verbally and via journal entries before scheduling testing. This assured a minimum accommodation period between fitting and testing of at least 21 days total for the duplicate socket and 7 days per foot condition in subjects' home environment (Fig. 2).

### OC and Familiarization

The local law enforcement and military OC were selected and approved as the test facility. It is routinely used to train police officers, SWAT team members, and various branches of military service members. SWAT operators and trainers were onsite at all times to familiarize and supervise participants during study training and assessment.

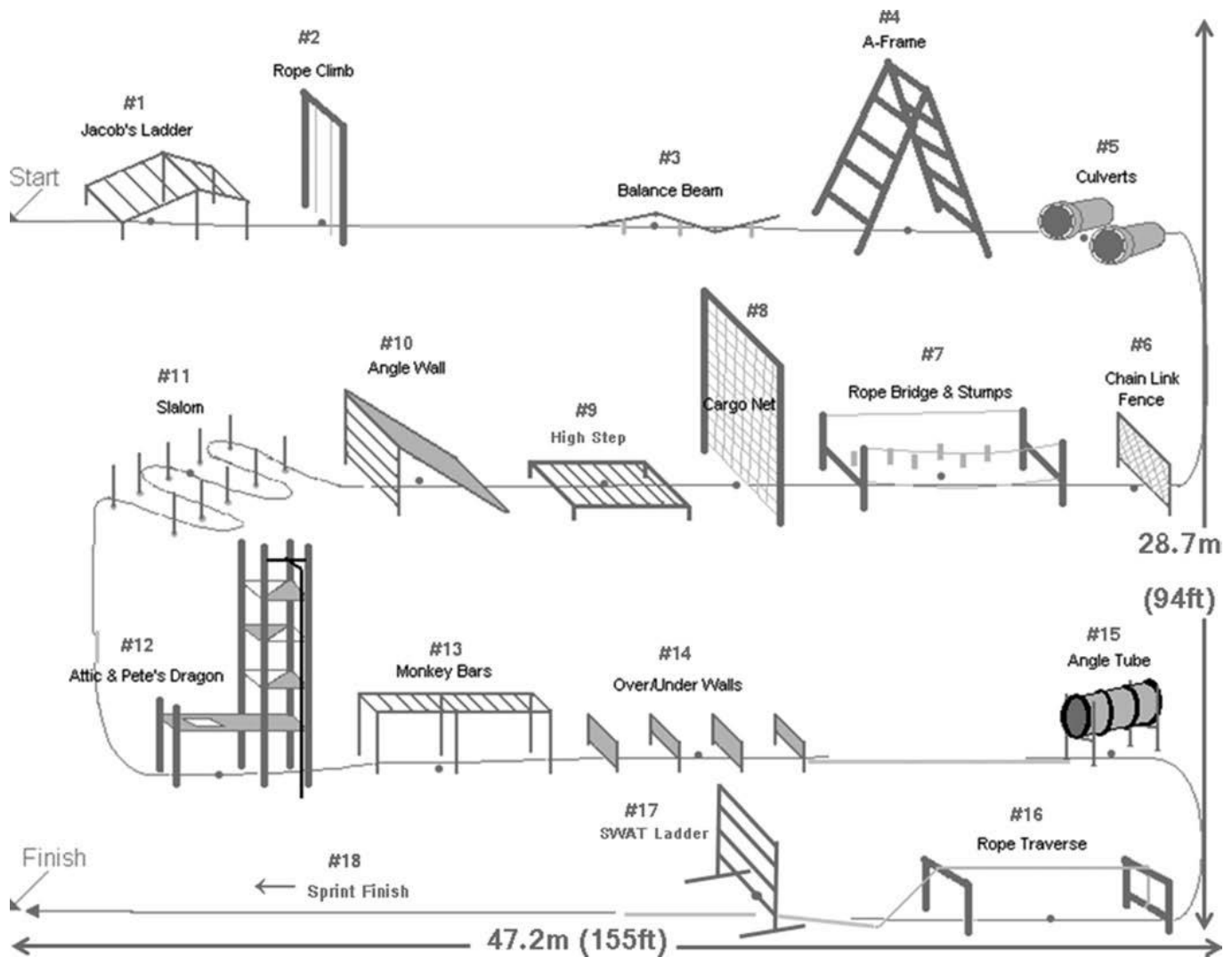
As recommended,<sup>25</sup> OC familiarization included three preparatory performance trials to eliminate confounding learning effects. The study familiarization and accommodation plan also included provision of an OC map (Fig. 3) to participants in advance of a physical familiarization and

training trip to the OC (Fig. 2). This included a 5-day prosthetic fitting and familiarization visit. Using their prestudy, preferred prosthesis, subjects visited the OC for instruction by SWAT operators on OC safety and completion technique. After instructional training and supervised practice, subjects performed three supervised OC trials independently, for a practice time.

The OC included the following obstacle tasks:

- (1) Jacob's Ladder
- (2) Rope Climb
- (3) Balance Beam
- (4) A-Frame
- (5) Culverts
- (6) Chain-Link Fence
- (7) Rope Bridge and Stumps
- (8) Cargo Net
- (9) High Step
- (10) Angle Wall (Fig. 4)
- (11) Slalom





**FIGURE 3.** Obstacle Course Map. This diagram shows the general lane and obstacle flow and sequence. It was provided to all participants in advance of initiating training and testing. Obstacle no. 2., the Rope Climb, is shown in this figure but was eliminated for safety reasons (see results section). Instructions for completion of this task during the training portion of the study were to vertically ascend the rope and touch the top pipe with a hand.

- (12) Attic and Pete's Dragon
- (13) Monkey Bars
- (14) Over/Under Walls
- (15) Angle Tube
- (16) Rope Traverse
- (17) SWAT Ladder
- (18) Sprint Finish

### Study Schedule

For the individual TTA subject, the study commitment involved 5 weeks of activity (Fig. 2) as follows:

Preparation period: Following enrollment and consent, the preparation period commenced. This was a 5-day session. The daily itinerary was as follows:

Monday: First meeting with a study prosthetist to initiate duplication of preferred socket. Preliminary fitting, adjust-

ment, and alignment of 3 prosthetic feet began on completion of socket duplication.

Tuesday: First training visit to OC. Subjects trained on OC sequence, completion technique, and safety. Visit with study prosthetist as needed.

Wednesday: Finalize prosthetic fittings adjustments and alignments.

Thursday: Second visit to OC. While supervised, subjects physically practiced OC. Visit with study prosthetist as needed.

Friday: Final meeting with study investigators, OC personnel, and study prosthetist.

Review accommodation period. Discuss and schedule the testing period.

Accommodation period: See "Prosthetic Fitting and Accommodation Period" section above.



**FIGURE 4.** All subjects were instructed to complete the course as fast as possible and as safely as possible. Subject is pictured traversing Angle Wall instructed to ascend the angle wall and either climb down the ladder on the back side or hop to the ground.

Testing period: Following accommodation, the testing period commenced. The testing period was a 5-day session as follows:

Monday: OC test 1 of 3 (randomized foot assignment)

Tuesday: Biomechanical and bioenergetic laboratory tests (reported elsewhere)

Wednesday: OC test 2 of 3 (randomized foot assignment)

Thursday: Biomechanical and bioenergetic laboratory tests (reported elsewhere)

Friday: OC test 3 of 3 (randomized foot assignment)

Biomechanical and bioenergetic laboratory testing involved minimal walking and running at comfortable speeds sufficient to achieve steady state yet insufficient to confound recovery between field test days. For control subjects, OC testing was completed in a single session. This is because of their routine (i.e., weekly) practice, assessment, and instruction with the course.

### Outcome Measures

Demographic information, anthropometric measures, fully assembled prosthetic masses, and final alignments (i.e., sagittal and coronal distances from LASAR line to manufacturer's recommended foot reference location) were recorded during the testing period before performance data collection. Using an ad hoc rating scale, subjects were also asked to rate their activity level (i.e., sedentary, minimally, moderately, or highly active) as well as to quantify the number and type of activity bouts per week and the number of years of participation. Subjects then completed the field OC, one time per foot (three times total) to determine total time-to-completion and

per-task completion times. Time data were recorded using laser timing gates (Brower TC-Gates, Brower Timing Systems, Power Systems, LLC, Knoxville, Tennessee) situated in front of and behind each obstacle on the OC.<sup>25</sup> As subjects would pass between the laser gates, times were triggered and recorded into a data file for later aggregation and processing. Immediately following each individual OC completion, subjects were asked to rate their perceived exertion (RPE) using the Borg (6–20) scale<sup>26</sup> for the entire course with the respective foot condition. Following the third and final OC completion, TTAs were asked to indicate which of the three feet conditions they preferred to utilize in order to complete the OC.

### Statistical Analyses

Sample size and power calculations were based on effect sizes calculated from performance outcomes (i.e., walking speed, oxygen uptake, lower limb joint kinetics, and perceived exertion) previously published regarding comparable high-functioning feet (e.g., Re-Flex Shock, Variflex, Ossur, Reykjavik, Iceland) in basic mobility tasks.<sup>7,13,27</sup> These estimates provided that 10 TTA subjects would adequately power the study with  $\beta = 0.80$ . Given the available data are from basic walking and running, the resulting sample estimates were regarded as conservative. Therefore, planning for attrition and accounting for the conservative estimates provided from basic mobility data, recruitment was set at 14 TTA participants. Following all assessments, data were entered into a database and verified before analysis. Subjects' performance data within a given condition (i.e., Variflex) were averaged (and variance calculated) to represent that condition for further analysis and comparison across conditions and between groups. Descriptive statistics were calculated (i.e., means, standard deviations) where possible. Continuous data (i.e., OC time to completion) were examined for normalcy and outliers using NCSS/PASS's omnibus calculation of skewness and kurtosis (2004 edition, Kaysville, Utah). A within subjects' repeated measures analysis of variance model was used to reveal statistical differences in performance between prosthetic feet conditions (dependent comparisons). Differences between control and experimental subjects were independent comparisons and thus ineligible for comparison using the repeated measures analysis of variance model. Therefore, depending on their distribution, either independent samples *t* tests (normally distributed data eligible for parametric analyses) or the Mann–Whitney *U* test was used to identify statistically significant differences between TTA and non-amputee controls (as independent comparisons per foot condition). The protocol's a priori level of significance was 0.05. All comparative statistical analyses were performed using SPSS 2012 v.20 (Armonk, New York). Finally, effect size was calculated using Cohen's *d*<sup>28</sup> and interpreted as  $d \geq 0.20$  represents a small effect,  $d \geq 0.50$  represents a medium effect, and  $d \geq 0.80$  represents a large effect

provided the related finding was statistically significant. Results were unmasked following all statistical analyses.

## RESULTS

### Subjects

A total of 28 participants provided informed consent and completed the protocol (i.e., no missing data). Of these, 14 were TTAs and the other 14 were members of the local Sheriff's SWAT team who served as nonamputee control subjects. The 14 TTAs included 5 Army Veterans, 3 Marine Corps Veterans, 3 accomplished civilian athletes, 2 active duty Army soldiers, and 1 active duty Air Force airman. TTAs lost their limbs  $8.9 \pm 10.5$  (mean  $\pm$  SD) years before enrollment primarily because of exposure to blasts from improvised explosive devices. Two of the civilian TTAs lost their limbs because of trauma and one was a congenital amputee. TTA subjects' mean age ( $31.4 \text{ years} \pm 5.9$ ) was significantly ( $p \leq 0.05$ ) younger than controls ( $38.5 \text{ years} \pm 5.1$ ). The TTA's body mass index was  $28.4 \pm 6.7 \text{ kg/m}^2$  compared to controls'  $26.3 \pm 2.9 \text{ kg/m}^2$  ( $p > 0.05$ ). Although 66.7% of TTAs rated themselves as highly active, only 35.7% of controls rated themselves as highly active ( $p > 0.05$ ). Self-reported activity (years and no. of bouts/week) was not significantly different between TTAs and controls, however, duration/bout was ( $p \leq 0.05$ ). Control subjects reported physical training of 2 to 5 bouts per week ( $3.1 \pm 1.1$ ) related to their work, whereas TTAs reported  $3.5 \pm 1.2$  (range: 1.0–5.0) bouts per week. TTAs reported training duration of  $62.7 \pm 24.3$  minutes compared to  $42.5 \pm 16.3$  reported by controls.

### Prosthetic Characteristics

TTAs reported using  $0.9 \pm 0.9$  (range: 0–3) additional recreational prostheses for the following activities; cycling, jogging/running, skiing, snowboarding, rock climbing, swimming, kayaking, soccer, and cross-fit exercise, which constituted much of the aforementioned physical training. Sagittal and coronal alignment of prosthetic feet setup for the study were to manufacturer specification and were not significantly different between conditions ( $p > 0.05$ ). In terms of prosthetic suspension, 9 subjects used a sleeve and 5 used a pin lock. Two of the subjects using pin suspension also used auxiliary suspension (one suction pin and one sleeve). All subjects used a total surface bearing socket design. Re-Flex Rotate ( $1.92 \text{ kg} \pm 1.10$ ) made prostheses significantly heavier ( $p < 0.05$ ; without socks/shoes) than the Variflex ( $1.67 \text{ kg} \pm 0.96$ ) and the Elite Blade ( $1.52 \text{ kg} \pm 0.96$ ).

### OC Timing Data

The OC includes 18 tasks. During the preparation period, the fitting and accommodation week, it became clear during OC practice that TTAs were greatly challenged by obstacle no. 2, the rope climb (Fig. 2, OC map). There were numer-

ous potential reasons including an inability to move the prosthetic ankle-foot system sufficient to use the feet to elevate the body and assist the upper limbs during climbing. Thus, SWAT operators determined the rope climb obstacle required elimination from further practice and evaluation for safety reasons. Removing the rope climb obstacle reduced the total number of tasks from 18 to 17 for both the TTAs and the control group. Following removal of the rope climb obstacle, total OC completion times (mean  $\pm$  SD) were similar ( $p > 0.05$ ) between prosthetic feet: Elite-Blade ( $419 \text{ seconds} \pm 130$ ), Variflex ( $425 \text{ seconds} \pm 144$ ), and Re-Flex Rotate ( $444 \text{ seconds} \pm 220$ ). Controls' total OC completion time was  $287.2 \text{ seconds} \pm 58$  which was less ( $p \leq 0.05$ ) than TTA times. In total, controls had significantly faster completion times ( $p \leq 0.05$ ) compared to all 3 prosthetic feet conditions in 13 of 17 obstacles (Table I).

The Re-Flex Rotate had two additional obstacles that were significantly different ( $p \leq 0.05$ ) than controls. The Elite Blade had one additional obstacle that required more time to complete. In terms of per-obstacle completion time differences between prosthetic feet, only two obstacles yielded differences: (1) climbing the chain-link fence and (2) the sprint finish. Climbing the chain-link fence required greater time with the Variflex than it did with the Elite Blade ( $14.0 \text{ seconds} \pm 4.9$  vs.  $12.4 \text{ seconds} \pm 4.6$ ;  $p \leq 0.05$ ). The sprint finish took significantly longer ( $p \leq 0.05$ ) to complete with the Re-Flex Rotate ( $6.6 \text{ seconds} \pm 1.7$ ) than it did with either the Variflex ( $5.9 \text{ seconds} \pm 1.1$ ) or the Elite Blade ( $5.9 \text{ seconds} \pm 1.4$ ).

### Perceptive Measures

Median RPE values were significantly lower ( $p \leq 0.05$ ) for controls (17; range: 14–17) than TTA regardless of foot condition (Variflex 18.5[15–20], Elite Blade 18.5[13–20], and Re-Flex Rotate 18[15–20]). Finally, when asked to rate their preference of foot for completing the OC, 7/14 subjects (50%) preferred the Elite Blade, 5/14 (36%) preferred the Re-Flex Rotate, and the remaining 2/14 (14%) preferred the Variflex.

## DISCUSSION

We hypothesized that the lightest weight foot would outperform other prosthetic foot alternatives and be the most preferred. We further hypothesized that nonamputees would outperform TTAs in all physical performance measures. The Elite Blade was the foot with the lowest mass, but it was not significantly different than the Variflex.

TTA subjects in this study are representative of combat injured military personnel and similar to TTAs from other studies of persons who have lost limbs in military service, in terms of demographic and anthropometric characteristics.<sup>1,2,4,6,29</sup> Among the more obvious results from this study were the differences in performance between TTA and control. TTAs were younger than controls by approximately



**TABLE I.** Time to Completion Data

Obstacle	Variflex		Elite Blade		Re-Flex Rotate		Control	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Jacob's Ladder	32.9	12.8	31.8	15.6	29.6	10.2	22.0*	8.2
Balance Beam	11.6	3.7	11.3	3.3	10.9	2.7	8.4*	1.7
A-Frame	39.6	14.4	37.0	11.6	36.6	13.9	23.4*	5.7
Culverts	14.0	3.8	14.4†	3.9	14.4†	3.3	12.0	1.8
Fence	14.0‡	4.9	12.4	4.6	13.2	4.0	8.6*	2.6
Rope Bridge	29.7	11.3	26.9	8.0	27.6	7.9	19.5*	5.2
Cargo Net	57.1	20.0	62.4	27.1	57.9	23.7	37.1*	6.9
High Step	13.9	5.5	12.4	2.9	12.1	2.4	9.8*	1.6
Angle Wall	11.7	4.8	11.1	3.5	14.9	17.0	7.0*	2.4
Slalom	14.2	3.5	13.6	3.0	14.5	3.2	13.8	1.6
Pete's Dragon	58.7	28.3	56.1	17.5	69.9	73.2	38.5*	7.6
Monkey Bars	20.7	8.4	20.9	7.2	21.7	8.4	14.5*	4.7
Over/Under Walls	20.9	11.4	19.5	6.6	19.4	8.3	14.3*	3.1
Angle Tube	17.1	9.9	16.6	7.4	21.3†	23.5	11.5	3.2
Rope Traverse	36.8	15.0	41.4	22.0	44.5	26.6	26.3*	9.6
SWAT Ladder	25.9	12.7	25.1	9.4	29.0	20.5	15.5*	4.7
Sprint Finish	5.9	1.1	5.9	1.4	6.6‡§	1.7	5.1	0.8
Total Time	424.7	143.9	418.9	130.2	443.9	219.9	287.2*	58.4

Time data are in seconds. Effect sizes (Cohen's  $d$ ) was large ( $d \geq 0.80$ ) for all statistically significant comparisons between prosthetic feet conditions and controls; small ( $d = 0.34$ ) for significant comparisons between Variflex and Elite Blade; and medium ( $d = 0.53$ ) for significant comparisons of Elite Blade with Re-Flex Rotate. \* $p \leq 0.05$  compared to all prosthetic feet conditions. † $p \leq 0.05$  compared to controls. ‡ $p \leq 0.05$  compared to Elite Blade. § $p \leq 0.05$  compared to Variflex.

7 years; however, controls had the advantage of familiarity and routine training on the OC facility. This familiarity controls had with the OC may account for some of the difference in performance; however, large performance differences between amputees and nonamputees are observed in multiple other reports.<sup>13,30</sup>

In 1995, approximately 2% of soldiers with major limb amputation returned to duty. With regard to OEF/OIF, there was an eight-fold increase (16%) of soldiers with amputation returning to duty.<sup>6,31</sup> One means for a soldier with amputation to demonstrate function beyond basic ambulation may be completing a military equivalent OC with performance comparable to nonamputees. For military applications, OCs are used to simulate impediments to tactical soldier movement that might be found in urban or rural settings.<sup>25,32</sup> OC completion speed may relate to fitness components such as upper and lower body aerobic and anaerobic power, muscular strength and endurance, and less quantifiable skill attributes such as agility and technique.<sup>23,25</sup> In military training, OCs have many intended functions including improving fitness, agility, confidence, and camaraderie.<sup>23,25</sup> Utilization of timed OCs for military performance assessment is important as multiple physiologic attributes contribute to overall performance in these tests and a tactical unit can only move as fast as its slowest member.<sup>17,21,25,32</sup> Therefore, removing the rope climb obstacle was a salient point in this study. SWAT operators' safety decision to eliminate the obstacle raised concern over the ability of TTAs, as a group, to complete the course. During training and accommodation, a small number of the TTA group were able to complete the task largely as an exclusively upper limb activity. This was

not advised by the trainers because many of the remaining obstacles require vigorous, reliable use of the upper limbs or a combination of upper and lower limbs. Therefore, completing the rope climb exclusively with the upper limbs created notable fatigue and compromised performance during the remainder of the course while participants were training and practicing. Hence, use of the feet to assist with the rope climb was advised. Unfortunately, TTAs were unable to oppose their prosthetic feet and ankles to create sufficient friction to enable the lower extremities to assist the upper limbs in lifting during the climb. This presented an obvious limitation of existing feet and ankle systems for TTAs in this task. It also prevented the TTAs, as a group, to be able to complete the course as originally designed. This, in addition to the 31% to 35% difference in overall performance, further highlights some of the impairment created by TTA. However, a few individuals in the TTA group were able to complete the course as designed. Although group analyses were necessary in order to meet study objectives, individual analyses may reveal considerable differences between TTAs. This observation that some individuals could complete the course, supports individual assessment for making return to duty determinations following injury related to combat or other facets of military service.

The mean number of additional artificial limbs used by subjects in this study was lower than that reported elsewhere.<sup>33</sup> In this study, TTAs reportedly used approximately 1 additional recreational prosthesis, thus having 2 prostheses in service, whereas others have reported an average of 3 prostheses. Although these two studies disagree over one additional prosthesis, the present study demonstrates an

objective level of utilization of these additional recreational/exercise prostheses and that their prescription appears to have the benefit of permitting the maintenance of high functional performance. That is, subjects in this study reported use of exercise prostheses, as opposed to their daily function limb, is what was used to maintain their fitness such that they were able to complete this rigorous OC with minimal modification.

Prosthetic socket design (total surface bearing) was consistent across all subjects, whereas suspension was not. That is, 64% of study prostheses were suspended via sleeve and the remaining 35% were suspended with a pin mechanism. There were no skin issues or subjective complaints at any point during the study to suggest suspension was a factor; however, it may bear consideration in future studies. Accommodation with study feet was 7 days per component in this study and 21 days with the duplicate socket. Socket accommodation was consistent with other transtibial studies who also reported 21 days.<sup>34</sup> In terms of feet components, the 7-day accommodation utilized here was substantially longer than the 30-minute accommodation<sup>35</sup> used in some foot studies, but notably shorter than the 4 weeks<sup>30,36</sup> used in others. There is no agreed on accommodation time for prosthetic componentry. Thus, confounding related to a lack of full accommodation can never be completely ruled out; however, we were confident subjects were proficient in the use of all study feet at the point of assessment.

Unlike other prosthetic considerations discussed thus far, the prosthetic foot design was the independent variable. One of the study's hypotheses was that foot mass would have been a key variable to impact function. The Variflex is an ESR foot shown to improve stride length and bioenergetic efficiency during ambulation, stair ascent kinetics, and to reduce fatigue. The other two feet studied incorporated both ESR and additional functions. The Elite Blade also incorporates vertical shock absorption and the Re-Flex Rotate incorporates vertical shock and torsional force absorption. These two additional features engineered into the Re-Flex Rotate increase component mass by 13% to 21% compared with the Variflex and Elite Blade, respectively ( $p \leq 0.05$ ).

Despite the significant difference in mass between components, the 1.4% to 5.6% difference between prosthetic feet in overall OC completion time was not statistically significant. However, in two specific tasks, climbing the chain-link fence and the sprint finish, use of the Elite Blade resulted in an 11.4% (compared to Variflex; chain-link fence) and a 10.6% (compared to Variflex and Re-Flex Rotate) reduced completion time ( $p \leq 0.05$ ). Although component mass may have been a factor, it is unlikely to have been the sole factor for the difference. Because the Elite Blade's energy storage and return capabilities, kinetics, ambulatory efficiency, and other factors have yet to be studied, it is not possible to determine which of these or other attributes of the Elite-Blade provide an advantage for these specific tasks. However, the addition of vertical shock function to an ESR foot has been shown to provide biomechanical advantages during

stair climbing and in ambulatory efficiency and may have played a role.<sup>13,27</sup>

Also noteworthy in terms of individual task function is the fact that use of the Re-Flex Rotate resulted in increased task completion time compared with the Variflex (10.6%;  $p \leq 0.05$ ). As previously mentioned, while evidence supports improved lower extremity stair-climbing kinetics and improved gait efficiency when ESR and vertical shock absorption are combined, authors were unable to locate evidence to suggest ambulatory speed increases with further addition of torsional force absorption. Conversely, during circular turning maneuvers, 1 report shows addition of a torsion adapter results in comparable movement speed.<sup>37</sup> These data suggest that some combination of additional component mass or the increased control needed to utilize the torsion adapter element of the Re-Flex Rotate, resulted in a decreased sprint time following a period of rigorous task completion. There are, however, clinical reports of benefits of torsional absorption in terms of favorable benefits to skin of the residual limb that may be preferable despite potential limitations to functional performance.<sup>38</sup>

The Re-Flex Rotate stood out in individual tasks compared with controls. Although control subjects completed the OC faster (31–35%;  $p \leq 0.05$ ), and completed 13/17 tasks faster ( $p \leq 0.05$ ) than TTA regardless of foot condition, controls were significantly faster than TTA when using Re-Flex Rotate for completing the culvert and angle tube obstacles (16.7% and 46.0%, respectively;  $p \leq 0.05$ ). These two tasks were not significantly different than controls when TTA used Elite Blade and Variflex feet. The culvert obstacle requires ducking to crawl through a concrete culvert (3 ft or 0.9 m diameter  $\times$  8 ft or 2.4 m length), standing up out of the first culvert, turning 180°, ducking and crawling through a second culvert (identical size). The angle tube is a plastic pipe (comparable size to the culvert obstacle) that must be crawled through after climbing upward into the pipe (3.8 ft or 1.2 m from the ground). The pipe is angled on a 4° incline so the subject exits the pipe 0.2 m higher than the start (4.7 ft or 1.4 m elevation). It is not clear how the Re-Flex Rotate may challenge function while crawling through the culverts unless perhaps the user is attempting to accept body weight through a transversely rigid foot that is rotating and thus requiring additional effort and time to control. In addition, on the culvert obstacle, the stand and turn maneuver may require added time and effort to control as does the climb into and landing from the angle tube obstacle. Nevertheless, use of the Elite Blade and Variflex did not result in significant time delays compared to controls as the Re-Flex Rotate foot condition did.

Perceptively, there were no significant differences between prosthetic feet. Variflex and Elite Blade yielded RPE (median) of 18.5/20, whereas Re-Flex Rotate yielded 18/20 immediately following OC completion. Although the Re-Flex Rotate's median RPE was lower, it yielded the same RPE range as Variflex (15–20), whereas Elite Blade yielded the lowest

RPE range at 13 to 20. Although no foot condition emerged as a clear overall advantage in this test battery, the Elite Blade yielded multiple trends of improvement which were given confirmation by being selected by half of study subjects while blinded to condition. Interestingly, more than twice as many participants preferred the Re-Flex Rotate relative to Variflex despite trends of performance advantages favoring Variflex. Considering other potential benefits of the Re-Flex Rotate, perhaps TTA are willing to trade nonsignificant differences in performance for greater comfort with this component. This finding is consistent with evidence-based practice, which places as much emphasis on patient preference as it does empirical evidence.

## LIMITATIONS

Although there were no skin-related or performance complaints to suggest suspension issues, suspension was not controlled and could be a factor related to performance. Study feet were not blinded during training and accommodation as study personnel felt it was important to train subjects on individual attributes of the feet. This could have led to some level of kinesthetic or other familiarity with the components that cued subjects to identification even while masked during testing. This could potentially be confirmed in future studies, however, the success of masking was not assessed. Also impacting results may have been the choice to acclimate subjects with study feet in a singular, extended time block as opposed to individually acclimating and then assessing with each foot. Finally, there are multiple statistical modeling approaches available to analyze these data. For instance, the OC used in this study could be viewed as a single task or as individual obstacle tasks. The primary hypothesis for this study sought to address overall performance. Thus, multitest correction was not incorporated into the analysis. Incorporation of multitest correction may have resulted in minor differences between prosthetic feet in individual obstacle outcomes, but would have been unlikely to impact overall outcomes.

## CONCLUSIONS

This study has quantified performance differences between highly mobile TTAs with optimized prosthetic componentry and able-bodied controls in a never before studied field OC environment. This could assist in determining the potential for retention of already trained soldiers following TTA.<sup>6,31</sup> Ultimately, nonamputee SWAT team members completed a military equivalent OC significantly faster and with less effort than a group of high-functioning transtibial amputees regardless of prosthetic foot condition. There were no clear differences in prosthetic feet when completing the OC; however, individual task performance, perceptive measures, and preference resulted in trends showing a slight improvement in performance with and preference for the Elite Blade, which is a dual function ESR foot combined with vertical shock absorption. Ultimately, patient preference should be

regarded highly during foot selection and prescription. Understanding how to maximally improve performance in such functional tasks may allow soldiers to best sustain physical fitness, return to their military occupational specialty and possibly in-theater duty. Data from this study have identified trends in the tested prosthetic feet to assist in optimizing performance in these activities, which can reduce wasteful costs associated with the current practice of trial-and-error foot selection based on anecdotal evidence.

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# Functional Outcomes of Service Members With Bilateral Transfemoral and Knee Disarticulation Amputations Resulting From Trauma

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**ABSTRACT** As longitudinal studies for those with bilateral transfemoral amputation (BTFA) or knee disarticulation (KD) are lacking, it is important to quantify performance measures during rehabilitation in an effort to determine reasonable expectations and trends that may influence the rehabilitation process. At initial evaluation (date of first independent ambulation) and follow up (median 135 [range = 47–300] days later), 10 participants with BTFA/KD completed 6 minute walk testing and Activity Specific Balance Confidence and Lower Extremity Functional Scale questionnaires. Of these, six participants also completed stair ambulation; ascent time and stair assessment index (SAI) scores were calculated. Patients utilized their prescribed prostheses at each visit. Participants were able to cover a significantly greater distance (135.3 [70.1] m) in 6 minutes at the follow-up visit (\* $p = 0.005$ ). The change in SAI scores for stair ascent and descent was not statistically significant ( $p = 0.247$ ). Stair ambulation confidence scores were significantly greater at the final visit (\* $p = 0.034$ ). Stair negotiation appears to plateau early; however, confidence builds despite absence of functional gains over time. Service members with BTFAs/KDs are able to achieve functional community ambulation skills. Thus, this investigation suggests that clinicians can realign rehabilitation paradigms to shift focus towards community distance ambulation once safe stair ascent and descent is achieved.

## INTRODUCTION

Recent conflicts in Iraq and Afghanistan have resulted in a cohort of individuals who have survived multiple limb amputation. The total percent of troops with multiple limb injury increased steadily throughout Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND).<sup>1</sup> Of those with extremity injuries, the estimated prevalence of multiple limb amputation is 30%, of which bilateral transfemoral amputation (BTFA) were most common (27%).<sup>1–3</sup> Transfemoral-level injuries are often among the most severe and require complex surgical and rehabilitative care.<sup>4–7</sup> Despite the increased prevalence of BTFAs compared to prior conflicts, the body of literature characterizing this injury group is minimal compared to that of persons with unilateral lower extremity limb loss.

One of first long-term follow-up studies of military service members (SMs) with BTFA was published by Dougherty in 1999, and the results were encouraging in terms of their adaptation of prosthesis, employment, and general well-being.<sup>7</sup> The presence of BTFA severely affects function but may not affect other quality of life metrics. Of the 30 veterans from the Vietnam War that were evaluated, 22% of respondents used prostheses for ambulation, and used them for an average of

7.7 hours per day, at mean time from injury of 27.5 years. Seventy percent were employed outside of their homes. The study group had lower physical functioning score on the Short Form-36 (SF-36) compared to a matched control group, but there was no significant difference between the groups in terms of pain, social functioning, general, emotional, and mental health.

SMs with BTFA from recent conflicts appear to have better health status, prosthesis adaptation, and mobility compared to SMs from prior conflicts. In a follow-up to their previous study, Dougherty et al (2012)<sup>8</sup> compared outcomes between 23 individuals with BTFA injured during the Vietnam War and 10 SMs who sustained BTFA during OEF, OIF, and OND. The OEF, OIF, OND group reported better health status, more frequent prosthesis usage, a greater number of prosthetic devices used, and mobility compared to the Vietnam group. However, the two groups reported similar quality of life. The greater number of prosthetic devices used is likely an indication of both the frequency of prosthetic care provided to the younger SMs and the provision of prostheses to allow participation in multiple specific training and recreational activities.

In the same year, Paul et al<sup>9</sup> reported on a retrospective analysis of outcomes from 25 Indian civilians with multiple limb amputation. In 12 patients with BTFA, 8 with bilateral transtibial amputation and 5 with mixed combination of the two levels of amputations, the authors found that there was no significant difference in the activities of daily living scores across groups. However, function was significantly greater for prosthesis users than nonusers, and this difference was greater for the BTFA group than other groups. The authors concluded that successful prosthetic rehabilitation appeared

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achievable independent of amputation level, although the small sample size limits the strength of their conclusion.

The largest study of war-related bilateral lower extremity amputations, published by Ebrahimzadeh et al,<sup>10</sup> found that SMs with BTFA have similar well-being and functioning as individuals with other amputations. The study included 291 Iran–Iraq War (1980–1988) veterans, and the Persian version of the SF-36 questionnaire was used to assess impact of amputation on health-related quality of life. The authors devised an ordinal grouping system based on the number of major joints impaired, grouping individuals with BTFA and hip disarticulation into a single group (Group V). This group comprised 25% of the study population, and the authors did not find the Type V groups to have different SF-36 scores than other groups; it is unclear if their finding is applicable specifically to the BTFA cohort due to their grouping system.

The lack of literature on gait and function of young, otherwise healthy SMs with BTFA is notable. Furthermore, all mentioned studies compare the rehabilitation outcomes between prosthetic and nonprosthetic groups. There is no literature describing benchmarks of rehabilitation or outcomes in the prosthetic BTFA group. As the literature has established the general favorable rehabilitation outcome in BTFA group, it is of vital interest for rehabilitation specialists to understand reasonable expectations and deficits of those who had achieved prosthetic ambulation in this group. The purpose of this study was to characterize physical recovery in SMs with BTFA, using objective and self-reported measures collected at two functional evaluations within the first year of independent ambulation with prostheses.

## METHODS

Ten SMs with combat-related bilateral transfemoral and/or knee disarticulation amputations, secondary to blast injury, participated in a large cross-sectional, longitudinal study of SMs with amputation. Institutional approval was provided by the local institutional review board and written informed consent was obtained before data collection. SMs were enrolled at the time they achieved the ability to independently ambulate without using assistive devices (all participated at zero-month time point) and then at follow-up evaluation within the next year. Inclusion criteria: age 18 to 45 years old; presence of BTFA; ability to walk independently without the use of an assistive device for at least 30 feet; ability to walk continuously for a minimum of 5 minutes; and visual analog scale pain score less than 4 out of 10. Exclusion criteria: moderate or severe traumatic brain injury; cardiac or pulmonary problems that limited physical activity; and post-traumatic stress disorder or other psychological condition that would be worsened by participation in the study. As a result of blast injuries, there were numerous comorbidities that did not preclude participation. SMs sustained any combination of additional injuries including trauma to one of both upper extremities (including amputation at transhumeral and/or transradial and/or multiple digits), abdominal and groin injuries (some requiring colostomies), tympanic membrane injury, as well as mild head trauma.

SMs completed all testing with their daily-use prostheses, consisting of microprocessor-controlled or mechanical prosthetic knee units and energy storing and return feet (Table I).

Data are reported on the following tests and questionnaires: 6-Minute Walk Test (6MWT), Stair Assessment Index (SAI),

**TABLE I** Demographics

Participants	Age (Years)	Time of Initial and Follow-Up Visit (Days From Injury)	Knee Type at Initial and Follow-Up Visit	Height at Initial and Follow-Up Visit (cm)	Weight at Initial and Follow-Up Visit (kg)
1	24	313	Cleg	175.5	73.1
		410	3R80	173.5	74.8
2	30	343	3R80	180	83.1
		464	CLeg	177.5	82.6
3	26	227	CLeg	176	57.5
		404	3R80	171.5	57
4	25	203	Rheo	182	70.8
		384	Plie	182	75.9
5	21	410	CLeg	169	84.2
		526	3R80	164	86.2
6	31	381	Genium	171.5	75.8
		428	Genium	169	75.4
7	22	210	CLeg	174.5	85.1
		335	CLeg	174.5	84.9
8	27	453	CLeg	169.5	84.1
		753	X2	175.5	92.2
9	23	404	X2	179	83.1
		501	X2	172	83.5
10	29	580	CLeg	174	87.5
		672	Genium	168.5	88.2
Average (SD)	25.8 (3.4)	357.1 (121.7)		175.1 (4.4)	78.4 (9.2)
		493.5 (147.9)		172.9 (5.4)	79.7 (10.5)

Timed Stair Ascent (TSA), Lower Extremity Functional Scale (LEFS), and Activity-Specific Balance Confidence (ABC) Scale. Scripted instructions were read to each SM for respective tasks.

The 6MWT is frequently used to assess aerobic fitness, endurance, and mobility.<sup>11,12</sup> Age-based normative times have been established in military and civilian personnel,<sup>11,13,14</sup> and the 6MWT is suggested as a reproducible measure of exercise tolerance.<sup>15,16</sup> The SMs were instructed to walk as far as possible in 6 minutes and the total distance walked was recorded.

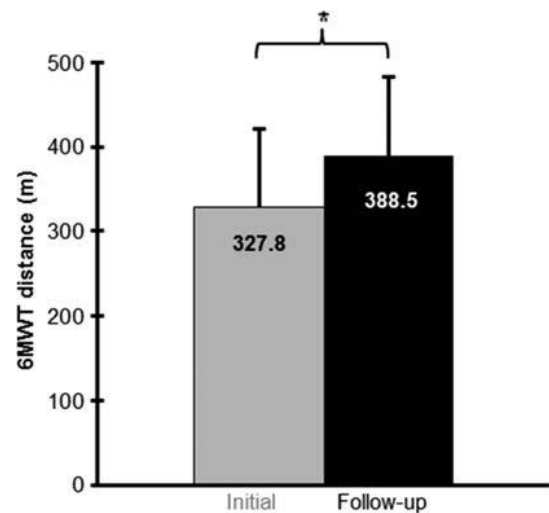
The SAI assesses functional ability while ascending or descending one flight of stairs. Scores range from 0 to 13 based on ability to perform the task, how the task is executed, and level of upper extremity support required.<sup>17</sup> Zero signifies inability to negotiate stairs and 13 represents reciprocal gait without use of a rail or assistive device. Ascent and descent are scored independently.

For the TSA, SMs were timed while safely ascending 11 stairs. They were required to touch each stair on ascent and completed 5 trials (with 1-minute rest in between). Time began when their foot hit the first stair and stopped when both feet were on the top platform. Timed stair climbing is often used as an objective measure of mobility and power, and has established test-retest reliability in older adults.<sup>18,19</sup> SMs were instructed to touch every step to the top of the staircase as quickly and as safely possible, turn around, and come back to the bottom. It was documented if the SMs needed to use the handrail, if needed, for safety. Every subject performed 5 trials with 1 minute of rest between trials.

The LEFS questionnaire, completed by SMs, involves a list of 20 activities that are rated on a scale from 0 (unable or difficult to perform) to 4 (able to perform without difficulty). This tool has been used in various patient populations to assess and track a person's ability to perform everyday tasks. It is often used as a baseline measure, and throughout the course of rehabilitation, to monitor progress and set functional goals.<sup>20</sup>

The ABC Scale is a self-report instrument used to evaluate an individual's balance confidence and fear of falling during functional activities.<sup>21</sup> It has demonstrated reliability and validity in older adults who have sustained an amputation; however, the psychometric properties of this instrument have not been specifically examined in younger adults following a traumatic amputation.<sup>22</sup> The ABC Scale has 16 items representing balance/functional activities, and the participant is asked to rate his/her confidence level in performing these tasks (using a scale of 0–100, with 0 = no confidence and 100 = complete confidence). The response to the following pertinent question is reported: "Do you or would you have any difficulty at all with going up or down 10 steps (about one flight of stairs)?"

Normality was determined using the Shapiro–Wilk test with a threshold value of  $p \leq 0.05$ . Between-session differences were evaluated using paired  $t$  tests for normally distributed data (participant height, participant weight, 6MWT, stair ascent time, and ABC score) whereas nonparametric

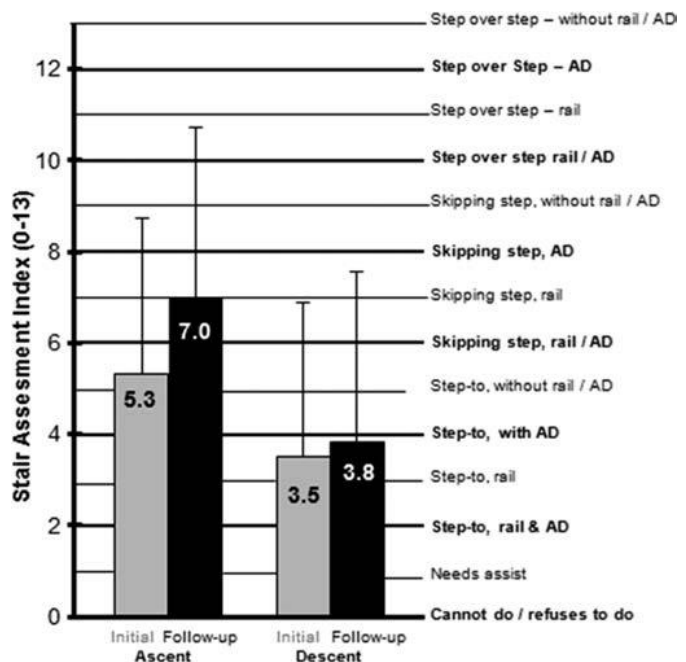


**FIGURE 1.** Results of the 6MWT show participants were able to cover a significantly greater distance (m) at the follow-up visit (\* $p = 0.005$ ).

data were assessed using the Wilcoxon signed-rank test. Significance was again set at  $p \leq 0.05$ . Effect sizes (Cohen's  $d$ ) were determined for performance measures.

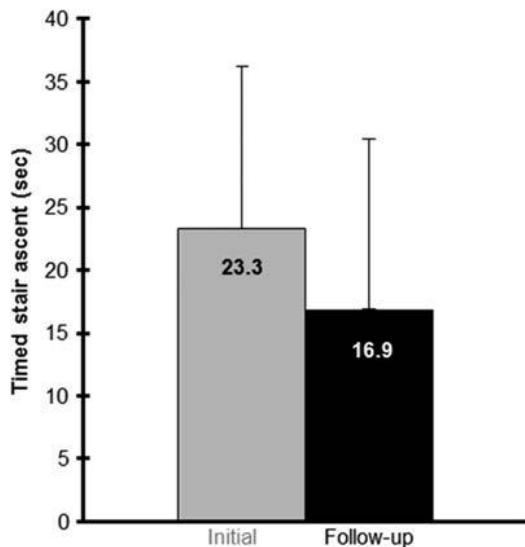
## RESULTS

The SMs had an average (SD) age of 25.5 (3.4) and time from injury of 352.4 (119.6) days at enrollment. It is important to note that the time to independent ambulation, as defined in the inclusion criteria of the study, was variable for the subject group (range = 203–580 days). The follow-up



**FIGURE 2.** Average method of stair ascent (left) and descent (right) as measured by SAI (Buell et al<sup>29</sup>) improved (increased) at follow-up visits for the six participants that completed stair functionality testing.

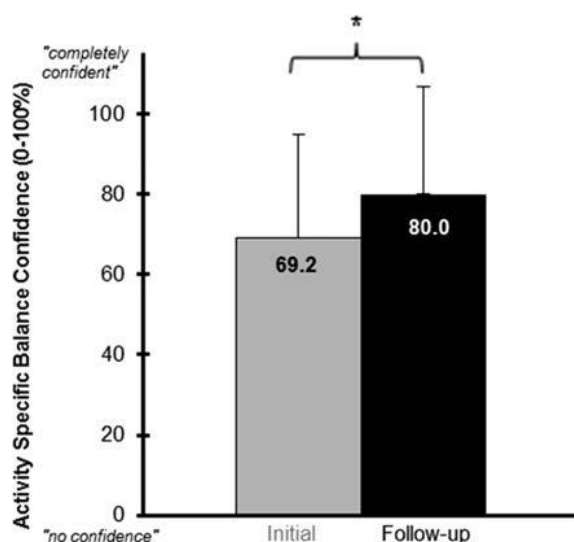




**FIGURE 3.** Although completion times varied between participants, the average time to ascend 11 stairs improved (decreased) by an average of 6.4 (11.9) seconds at the follow-up visit.

evaluation was completed on average 135 (47–300) days after initial evaluation. Although leg length can be readily modified for individuals with bilateral amputation, height did not significantly differ between sessions ( $p = 0.386$ ); all but one participant was either the same height or slightly shorter at the final visit. Weight did not change between sessions ( $p = 0.452$ ) with all but two SMs staying within 2.0 kg of initial weight. All SMs completed LEFS and 6MWT testing. Only 6 of 10 SM completed stair testing at both initial and final visits, and only those with initial and follow-up stair function data were included.

At the follow-up visit, all SMs were able to cover significantly more distance within 6 minutes ( $p = 0.005$ ,  $d = 0.76$ ).



**FIGURE 4.** Average stair ambulation confidence score, as recorded by ABC evaluation, was significantly greater at the final visit (\* $p = 0.034$ ).

On average, SMs gained 135.3 (70.1) m between sessions (Fig. 1). The mean distance traveled in 6MWT at the final collection of this study was 389 (94) m.

Average SAI ascent scores were 5.3 (4.0) initially and 7.0 (4.4) at follow-up, but the difference was not significant ( $p = 0.102$ ,  $d = 0.40$ ; Fig. 2). The average SAI descent scores did not increase significantly between sessions (3.5 [3.4]–3.8 [3.7];  $p = 0.66$ ,  $d = 0.09$ ; Fig. 2).

There was no significant change ( $p = 0.247$ ,  $d = -0.49$ ; Fig. 3) in mean time to ascend stairs between initial and final visits.

The initial self-reported value of LEFS scores was reported as 3.0 (0.9) with a final value of 3.5 (0.5), which was not statistically significant ( $p = 0.059$ ,  $d = 0.66$ ).

Mean balance confidence during stair ascent increased from 69.2% (19.7) on a 0 to 100% scale at the first visit to 76.8% (21.1) at the final visit; the difference was not statistically significant ( $p = 0.34$ ,  $d = 0.36$ ; Fig. 4).

## DISCUSSION

Longitudinal outcomes data are lacking for individuals who have experienced BTFA. Functional outcomes data can play a valuable role in clinical treatment planning as data can be used to objectively track recovery over time and identify factors that may influence the rehabilitation process. Many SMs with BTFA are able to return to functional community ambulation but require more time than uninjured individuals to complete gait-related tasks. Therefore, the data presented provide insight into the functional abilities of SMs with BTFA at the point of independent ambulation and progress during the first year of rehabilitation.

As a group, initially these SMs with BTFA demonstrated large deficits in the 6MWT compared to uninjured controls. However, mobility did improve over the course of rehabilitation as seen in the increase in distance traveled during the 6MWT. In fact, the average distance traveled increased from 327.8 (75.0) to 388.5 (93.8), which was much closer to the 452 (141) m previously reported for those with unilateral TFA.<sup>23</sup> Remaining differences could be because our SMs were tested earlier in the rehabilitation process, relative to those with unilateral TFA who were on average 2.3 years' postamputation.<sup>23</sup> The average distance of SMs with BTFA at follow-up was still much less than the distance traveled by uninjured controls: 761 (87) m.<sup>23</sup> These results provide a 6MWT milestone for those with BTFA.

Many aspects of mobility did not improve beyond the point of independent ambulation. Although subjective ABC score significantly improved, objective improvement was not observed in the SAI during ascent or decent, the LEFS, or the TSA. Ascending stairs requires greater strength and motion than level-ground walking,<sup>24</sup> and not surprisingly, several SMs were unable to complete the task at initial assessment. The lack of statistically significant changes in the SAI score, the ABC score, and the LEFS score shows the difficulty of completing important functional tasks in

individuals with BTFA. Difficulty with stairs is well documented in those with lower extremity amputations. De Laat et al<sup>25</sup> reported that in unilateral TFA and knee disarticulation group, the success rate of achieving independent stair ambulation after outpatient rehabilitation is 60% without rail and 16% without handrail. Hobara et al<sup>24</sup> demonstrated that time from injury has a positive correlation with the SAI in unilateral TFA, but published literature relies on patient report rather than direct observation with patients that were more than 17 years postamputation. We see a trend in decreasing time required to ascend stairs in SAI, but not in the time required to descend stairs. The ABC and LEFS questions combine stair ascent and descent within the same questions, so we cannot determine if these instruments also reflect different trends between ascending and descending stairs observed in SAI. There are several possible explanations for our findings. The improvement of stair ascent time may be indicative of gains in strength, balance, coordination, and motor control sufficient to achieve the task more rapidly. Descending stairs poses greater risk of injurious falls,<sup>26</sup> and individuals with BTFA must rely on resistance in the prosthetic knee to control the lowering from 1 step to the next. Therefore, the lack of SAI improvement during descent of stairs may be influenced by comorbidities, e.g., muscular deficits, or inherent prosthetic limitations contributing to mistrust of the prosthesis. In addition, the lack of statistically significant improvement in these assessments over time indicates that the ability to navigate stairs in individuals with BTFA may plateau early without any significant improvement overtime.

These findings have practical impact in guiding rehabilitative therapies and prosthetic design. During the first year of independent ambulation, although efforts may have been made to improve safety or quality of movement, there were no systematic improvements over time during stair ambulation. Clearly, individuals with BTFA demonstrate deficits in physical performance relative to their able-bodied counterparts.<sup>7</sup> However, in the 6MWT, these SMs performed close to civilians with unilateral transfemoral amputations. These findings, combined with the fact that this generation of SMs report confidence in stair negotiation and are wearing and walking in their prostheses more than the previous generations of SMs,<sup>8</sup> might suggest that clinicians should realign rehabilitation paradigms for those with BTFA. Training emphasis may be better placed on other movements required for daily living. Although stairs negotiation is limited, expectations can be increased in the area of community distance ambulation. Prosthetic development should focus on incorporating these seen restrictions into new devices. Progress remains hopeful as the prosthetic industry is incorporating new materials and advanced prosthetic technology into current designs.<sup>27,28</sup> These advances will likely further increase expectations in terms of rapid recovery rates, quality of life measures, and ability to return to occupation and leisure activities despite high-level injuries such as BTFA.

Several limitations should be considered when interpreting the results of this study. First, there are inherent differences between the study population and the general population. Military SMs are generally in better physical condition than their civilian counterparts. In addition, the heterogeneity and complexity of injuries sustained by SMs differ from amputations incurred by civilians. Injuries sustained from improvised explosive device blasts are rarely confined to the severed extremity and result in injury of varying severity to adjacent body parts. Any comorbidities can impact the rehabilitation process, likely adding variability to study results thereby influencing the ability to detect changes over time. Also, the SMs were treated in a military treatment facility that is highly specialized in the rehabilitation of traumatic war injuries. They underwent intensive rehabilitation managed by multidisciplinary teams with years of experience in surgical management of war-related traumatic amputation and soft tissue injuries, pain management, and prosthesis prescription, fabrication, fitting, and troubleshooting. Furthermore, military treatment facilities provides a dedicated environment where SMs can focus on returning to premorbid level of function, with minimal distraction from family needs and financial pressure. These inherent differences limit the generalizability of the finding in this study into non-military population. Other limitations include the time period between initial and follow-up evaluations being variable from patient to patient. Lastly, though we detected generally favorable changes in the tested instruments, only improvements in 6MWT and ABC reached statistical significance, and we found no significant changes in the stair ambulation.

In summary, we showed that through intensive rehabilitation, the recovery of SMs with BTFA is generally favorable, with statically significant improvement in walking distance over the first year of independent ambulation, while the improvement of their stairs ambulation function remained static. These findings can be used to help set outcome expectation as well as rehabilitation guidelines.

## ACKNOWLEDGMENTS

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# Core Temperature in Service Members With and Without Traumatic Amputations During a Prolonged Endurance Event

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**ABSTRACT** Introduction: Service members with traumatic amputations may be at an increased risk of elevated core body temperature, since their ability to dissipate heat may decrease with the reduction in body surface area (BSA) after injury. Elevated core temperature can impair physical performance during combat operations potentially putting the service members and their teams at risk. The purpose of this study was to compare core temperature between individuals with and without amputations during a prolonged endurance event. Materials and Methods: Twenty healthy male military service members (10 with amputations, 10 without) participated in the Bataan Memorial Death March 26.2-mile event on March 27, 2011. Data collected include BSA, body mass index, body composition, body weight before and after the event, core temperature during the event, and postevent hydration status. Body composition was measured by dual-energy X-ray absorptiometry. Body weight was measured by digital scale. Core temperature was measured by ingestible sensor. Hydration was measured by urine specific gravity. The Walter Reed Army Medical Center Institutional Review Board approved this study and participants provided written informed consent. Results: Three participants' data were not included in the analyses. No significant differences in core temperature were found between participants in both groups, and no correlation was found between core temperature and either BSA or hydration status. There was no significant difference in maximal core temperature between the groups ( $p = 0.27$ ). Nearly all participants (8 control, 6 amputation) reached 38.3°C, the threshold for increased risk of heat exhaustion. No subjects reached 40.0°C, the threshold for increased risk of heat stroke. Time spent above the 38.3°C threshold was not significantly different between groups, but varied widely by participant in relation to the duration of the event. Participants without amputations finished the event faster than participants with amputations ( $7.9 \pm 1.4$  vs.  $9.6 \pm 0.96$ ,  $p < 0.01$ ), possibly indicating that participants with amputations self-selected a slower pace to attenuate increased core temperature. Conclusion: Until conclusive evidence is accumulated, it is prudent for military leaders, trainers, and military service members to closely monitor this population during physical activity to prevent heat injuries.

## INTRODUCTION

Heat illness and injury continue to be a concern for the military with 2,027 documented incidences of heat stroke/injury in active duty service members in 2014.<sup>1</sup> Elevated core temperature has harmful effects on the brain, liver, muscles, and kidneys, and can significantly impair a military service

member's physical performance.<sup>2</sup> When service members develop heat illness and injury during combat, their team's capabilities degrade placing all team members at risk. Determining who is more likely to suffer heat illness, and developing strategies to mitigate the risk, may increase the safety of the entire combat team.<sup>3</sup>

From September 2001 to 2014, 1,573 military service members suffered traumatic major limb amputations as a result of combat operations.<sup>4</sup> The proportion of U.S. service members remaining on active duty after undergoing amputations has increased from 2.3% in the 1980s to about 16.5% in 2010.<sup>5</sup> Many of these active duty service members return to combat operations conducted in harsh environmental conditions. Anecdotal information suggests that service members with amputations report feeling hotter than before their amputation, and experience more profuse sweating during activity.

Individuals with amputations may be at higher risk for experiencing elevated core temperature during exercise than their uninjured counterparts, potentially due to increased heat production and/or decreased dissipation ability. Exercise intensity significantly impacts the amount of heat produced during exercise<sup>6</sup> and persons with amputations have higher levels of energy expenditure when performing the same task, such as walking, as persons without amputation.<sup>7</sup> Body surface area (BSA) plays a significant role in the body's ability to regulate core temperature and dissipate heat.<sup>2,8</sup> Individuals with amputations have decreased BSA and frequently their

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residual limbs are covered with a prosthesis, both of which may decrease the ability to dissipate heat. Hindrance to any thermoregulatory mechanisms may increase the risk of heat injuries.<sup>2</sup>

To date, there is only one published pilot study comparing the core temperatures of service members with and without amputations leaving open to discussion whether service members with amputations are more susceptible to heat injuries than their counterparts without amputations.<sup>9</sup> The primary objective of this study was to determine if individuals with amputations were more predisposed to heat illnesses than individuals without amputations by comparing core temperature during a prolonged endurance event. We hypothesized that individuals with amputations would have higher core temperatures than individuals without amputations. Secondary objectives included determining how BSA and hydration status affected core temperature in individuals with and without amputations during a prolonged exercise event. We hypothesized that decreased BSA would be directly correlated with higher core temperature while hydration status would be inversely correlated.

## METHODS

The current study is a case-control investigation to test whether individuals with amputation are at increased risk of heat injury while performing duties typical to military service, this study was conducted during the Bataan Memorial Death March (BMDM), a 26.2-mile road march in New Mexico, on March 27, 2011. The event mimics extended marching frequently performed by many operational military forces.

Twenty participants from a convenience sample of service members planning to participate in the event volunteered for this study: 10 with amputations and 10 without amputations served as a control group. The participants with limb loss included 7 participants with a unilateral trans-tibial (below the knee) limb loss, 1 participant with a unilateral transfemoral (above the knee) limb loss, 1 participant with unilateral transradial limb loss, and 1 participant with unilateral transhumeral limb loss. The range in time since amputation was 6.97 to 39.87 months (mean 15.10 months). All participants were recruited from teams at Walter Reed Army Medical Center, Washington, DC, and Joint Base San Antonio, Texas who were trained and had already registered for the event. Participants were contacted by the study team during training sessions for the event or by word of mouth upon referral from the medical staff. The Walter Reed Army Medical Center Institutional Review Board approved the protocol and all participants provided written, informed consent. Research team members met with participants at their respective sites before the pre-event data collection session in order to explain the study and study-related risks.

All participants were active duty or retired service members. Participants with amputations were required to have had at least 6 months of prosthesis usage before the event

and a physician cleared all participants who were still undergoing medical treatment. Participants were excluded from the study if they had previous heat injuries, nontraumatic amputations, neurological, cardiovascular, pulmonary, orthopedic, or other conditions or medications that would contraindicate completion of a 26.2-mile march or swallowing an ingestible sensor.

Data collected before the event included height, weight, body composition, body mass index (BMI), and BSA. Pre-event weight was collected just before the start. During the event, core temperature was monitored using ingestible core temperature sensors. Following completion of the event, event duration was recorded and postevent weight and urine specimen were collected. All participants wore comfortable attire and shoes or boots during the event.

Body composition and background information were collected within 4 weeks of the event. Background information included age, gender, and the date and level of any amputation. Body weight was measured on a calibrated digital scale to the nearest 0.1 kg. Participants reported their height from their last preinjury physical fitness test. This is an official military measurement conducted according to precise standards.<sup>10</sup>

BMI was calculated using standard calculations ( $\text{kg}/\text{m}^2$ ). Adjusted weight was used for participants with amputations. Adjusted body weight was calculated as current body weight/ $(1 - P)$ , where  $P$  is the proportion of total body weight represented by the missing limb or limbs.<sup>11</sup>

BSA was calculated using the Mosteller (1987) formula, the preferred method in clinical medicine for determining BSA:<sup>12</sup>

Without amputations:  $\text{BSA} (\text{m}^2) = (\text{H}[\text{cm}] \times \text{W}[\text{kg}]/3,600)^{0.5}$

With amputations:  $\text{BSA} (\text{m}^2) = \text{BSA} - ([\text{BSA}] \times [\% \text{ BSA part}])$

Percent (%) BSA part reflects the level of amputation of the missing limb or limbs.<sup>13</sup> Calculated BSA for participants with amputations used adjusted weight and excluded the area covered by the prosthesis liner.

Body composition was measured by dual-energy X-ray absorptiometry (DXA Windows XP version QDR software, Hologic, Discovery-Wi, Bedford, Massachusetts). Data collected include lean mass, fat mass, and body fat percentage. Participants were scanned in minimal clothing with prostheses, jewelry, and metal objects removed.

Participants were weighed on site using a calibrated digital scale before and after the event to account for fluid loss. Participants consumed food and beverages ad libitum during the race. Urine samples were taken immediately after participants completed the BMDM to assess hydration status. Urine-specific gravity (USG) was assessed using a calibrated hand-held refractometer (model HR-200 ATC, AFAB Enterprises, Eustis, Florida).

Calibrated temperature sensors (CoreTemp, HQ Inc, Palmetto, Florida) were distributed to the participants the night before the event and ingested by participants the



following morning approximately 2 hours before starting the event. In previous studies, ingesting the sensor 4 to 6 hours prior was optimal; however, due to the projected event duration, a shorter lead-time was chosen to minimize early excretion of the sensor during the event.<sup>14,15</sup> Once ingested, the sensor telemetrically transmitted core temperature data every 10 seconds to an external receiver worn on the participant's waist. The data were downloaded from the receiver to a study laptop after the event. Minimum and maximum air temperature were recorded for the day of the race.<sup>16</sup>

### Statistical Analysis

Data are presented as mean  $\pm$  SD. Core temperature data were processed to provide 5-minute averages for the duration of the event. The primary outcome variables of interest were maximal core temperature, time to reach maximal core temperature, time to 38.3°C, time above 38.3°C, time to 40°C, and time above 40°C. These core temperature levels were chosen based on risk of heat exhaustion and heat stroke, respectively.<sup>17</sup> Group temperature means and demographic data were compared using an independent *t* test. Levene's test for equality of variance was used to ensure assumptions of normality were met for the two groups. Pearson's correlations were used to assess the relationship of maximal core temperature and time above 38.3°C to event duration, hydration status (USG), BSA, and BMI.

Statistical analyses were conducted using the PASW Statistics 18 (SPSS Inc, Chicago, Illinois). A priori power calculation suggested that with group sample sizes of 10 each, there was 80% power to detect a difference of 0.59°C between groups with significance level of  $p < 0.05$ .

### RESULTS

All participants started the BMDM. Two participants (1 trans-tibial, 1 transfemoral) with amputations did not finish the event: one due to prosthesis malfunction and a second opted to complete the 15.2-mile honorary march due to pain. Data for these participants were not included in the analysis. One control group participant's temperature reader malfunctioned rendering the data unusable. As a result, data from 17 participants (9 control, 8 amputation) were used in the analyses. The groups were well matched in anthropometrics, with the exceptions that the control group was older ( $p = 0.029$ ) and the amputation group was taller ( $p = 0.038$ ) (Table I).

There was no significant difference in maximal core temperature between the groups ( $p = 0.27$ ) (Table II). Nearly all participants (8 control, 6 amputation) reached the threshold of 38.3°C (Fig. 1). Maximal core temperature for the amputation group ranged from 38.2 to 38.8°C. For the control group, maximal core temperature ranged from 38.1 to 39.0°C. No subjects reached 40.0°C. Time spent above the 38.3°C threshold was not significantly different between

**TABLE I.** Participant Demographics for Participants With and Without Amputation

	With Amputation ( <i>n</i> = 8)	Without Amputation ( <i>n</i> = 9)
Age (Year)	26.1 $\pm$ 3.6*	33.3 $\pm$ 7.7
Height (cm)	181.9 $\pm$ 5.2*	176.4 $\pm$ 4.8
Weight (kg) <sup>a</sup>	92.3 $\pm$ 18.9	84.4 $\pm$ 11.2
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	27.8 $\pm$ 4.5	27.2 $\pm$ 4.1
BSA Adjusted <sup>b</sup>	4.46 $\pm$ 0.98	4.14 $\pm$ 0.55
Body Fat %	18.0 $\pm$ 8.9	19.6 $\pm$ 5.5
Muscle Mass (g)	65,996 $\pm$ 10,918	63,685 $\pm$ 5,629
Fat Mass (g)	18,978 $\pm$ 8,527	16,773 $\pm$ 6,667

Data are mean  $\pm$  SD. <sup>a</sup>Weight for amputation group is adjusted to account for missing limb proportion; adjusted weight used to calculate BMI for same subjects. <sup>b</sup>BSA for amputation group is adjusted to account for missing limb proportion. \*Significantly different than control group at  $p < 0.05$ .

groups (Table II) but varied widely by participant in relation to the duration of the event.

The control group finished the event faster than the amputation group ( $p = 0.01$ ). There was no significant correlation between event duration and time above 38.3°C or max core temp (Fig. 1). There were no significant correlations between hydration, BSA, and BMI with either maximal core temperature or time above 38.3°C.

### DISCUSSION

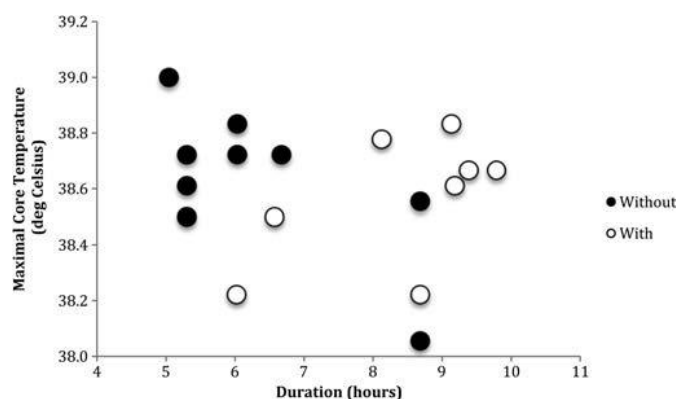
The primary objective of this study was to compare changes in core body temperature in individuals with and without amputations during a prolonged endurance event. Although we hypothesized that participants with amputations would have higher core temperatures than participants without amputations during the 26.2-mile BMDM, the data collected did not support this hypothesis. Specifically, all metrics were similar between the two groups, except time to completion.

When walking at similar speeds individuals with amputations may expend up to 33% more energy than individuals

**TABLE II.** Event Measures for Participants With and Without Amputation

	With Amputation ( <i>n</i> = 8)	Without Amputation ( <i>n</i> = 9)
Maximum Core Temperature (°C)	38.56 $\pm$ 0.23	38.64 $\pm$ 0.26
Time to Maximum Core Temp (Minutes)	390 $\pm$ 124	344 $\pm$ 143
Time to 38.3°C (Minutes)	293 $\pm$ 161	206 $\pm$ 178
Time Above 38.3°C (Minutes)	101 $\pm$ 83	128 $\pm$ 113
USG Postevent	1.021 $\pm$ 0.011	1.022 $\pm$ 0.008
Weight Loss at End of Event (kg)	1.55 $\pm$ 1.12	1.72 $\pm$ 1.01
Weight Loss %	1.78 $\pm$ 1.32	1.87 $\pm$ 1.08
Duration of Event (Hour)	9.6 $\pm$ 0.96*	7.9 $\pm$ 1.4

Data are mean  $\pm$  SD. \*Significantly different than control group at  $p = 0.01$ .



**FIGURE 1.** Maximal core temperature in relation to duration of event in participants with and without amputation.

without amputations.<sup>7,18,19</sup> Although participants with amputations marched at a slower pace than their counterparts, they may have been working at a similar metabolic rate due to gait differences observed in previous studies.<sup>20</sup> Metabolic rate during exercise is an important determinant of core temperature,<sup>21</sup> which may explain the similarities in core temperature between groups in the present study.

Similarly, heavy exercise in hyperthermal conditions at a constant workload or pace is associated with limited performance time and greater oxygen uptake.<sup>22</sup> In marathons where an individual is able to self-select pace, pace was slower by 2% in elite runners and 10% in less-trained runners as the ambient temperature increased.<sup>23</sup> We suspect that participants in the BMDM inherently adjusted their pace to mitigate the metabolic-related increase in core temperature, thereby affecting their time to completion.

Participants without amputations were slightly older on average than the group with amputations. However, studies conducted in hot environments have shown that age does not significantly affect thermoregulatory function.<sup>24,25</sup>

One of the most frequently reported reasons for not wearing a prosthesis is heat and consequent sweating of the residual limb.<sup>26,27</sup> We hypothesized that the prosthesis and liner could inhibit heat dissipation, which might cause core body temperature to rise more substantially and quickly with exercise. The variables of BSA and adjusted BSA with prosthesis liner, however, did not significantly correlate with core temperature. Seven of the 9 participants with amputations had transtibial amputations, which made comparisons between levels of amputation, and therefore BSA, more challenging.

There was no correlation between hydration status and maximum core temperature ( $r = 0.09$ ,  $p = 0.69$ ), consistent with other research conducted in an outdoor environment.<sup>28,29</sup> Participants in this study lost less than 2% of their body weight, which is under levels previously reported to affect core temperature and within the guidelines for hydration during exercise.<sup>3,30</sup> Previous studies have shown that adequate fluid replacement during exercise may help attenu-

ate the rise in core temperature.<sup>31</sup> Unlike this study, however, many of those studies controlled fluid intake.<sup>32</sup>

It is possible that the relatively mild temperatures during the BMDM, which ranged from 12 to 23°C, were not in the hyperthermal ranges tested in other studies that showed significant differences between conditions.<sup>22,23</sup> The low relative humidity of 10 to 25% and average wind speed during the BMDM ranged 5 to 15 miles per hour most likely assisted in heat dissipation,<sup>2,3</sup> as well.

The main limitation in this study is the small sample size and possibility of a type 2 error. The loss of three participants degraded the ability to detect statistical differences and required the analyses to be limited in complexity. A larger sample size would allow analyses that controlled for the effect of all of the covariates on core temperature during exercise. To provide a more complete understanding of the role of hydration and sweat rate in body temperature regulation, future studies should monitor fluid intake, food intake, and urination during the event, in addition to weight before and after. The results are promising, though, in suggesting future research related to the effect of workload or pace on core temperature.

The results of this study suggest that people with amputations may not be at higher risk for heat injury when exercising at a self-selected pace in moderate conditions. Until conclusive evidence is accumulated, however, it is prudent for trainers and military service members to closely monitor this population during physical activity to prevent heat injuries. Future research that is adequately powered is needed to fully investigate the potential differences in core temperature between service members with and without amputations during prolonged exercise. Additional research should be performed in additional conditions with greater heat stress to validate the preliminary findings of this study will ensure adequate safety protocols are developed and procedures are implemented to decrease risk of heat injury for military service members and athletes with and without lower limb amputation.

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## A Review of Unique Considerations for Female Veterans With Amputation

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**ABSTRACT** This article explores unique considerations that face both women living with limb loss and their health care providers. This demographic of patient has a higher rate of artificial limb rejection, thus challenging providers to address needs for cosmesis and function that varies from those of male counterparts. Health care providers for women with amputations, such as the Veterans Affairs, must evolve health care delivery, research practices, and work jointly with industry in order to meet the needs of this population.

Of the estimated 1.6 million people living with limb loss in the United States in 2005, approximately 35% were female. Among the Americans living with amputation, 45% were of traumatic etiology and 19% of this subgroup were female.<sup>1</sup> Despite these numbers, females with amputation are studied less than their male counterparts in prosthetic and amputee rehabilitation research thereby limiting evidentiary support for clinical decision-making in this demographic.

Within the U.S. Department of Veterans Affairs (VA), female Veterans represent an expanding component of the overall Veteran population. Nine percent of the overall Veteran population is female,<sup>2</sup> and women make up 12% of the personnel for Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND). Female Veterans with amputation make up approximately 2% of the Veteran amputee population. In 2013, the Veterans Health Administration served 1,805 female Veterans with amputations including 53 who served in OEF/OIF/OND.

A 2012 report from the VA Office of the Inspector General cited OEF/OIF/OND Veterans with amputations are significant users of all health care services and require comprehensive interdisciplinary care to meet their needs.<sup>2</sup> Within VA, female Veterans with amputation are seen more frequently for rehabilitative and prosthetic services than their male counterparts. Providers caring for female amputees should consider that one in five female Veterans screen positive for military sexual trauma and they are 22% more likely to be diagnosed with a mental health condition compared to male Veterans. Additionally, female Veterans are twice as likely to be homeless<sup>3</sup> and have a higher unemployment rate

for 25- to 44-year-olds compared to female non-Veterans in the same age range in the United States.<sup>4</sup> Of all women with amputation that have domiciles, 57% are likely to live alone compared to 36% of males with amputations.<sup>5</sup>

Women generally require smaller prosthetic components compared to men because of their smaller bone structure and muscle mass.<sup>6–9</sup> Commercially available prosthetic components are not gender specific and may be designed more with typical male anthropometry, biomechanics, and function in mind. Therefore, dissatisfaction with prosthetic fit and appearance tends to be higher in the female population living with limb loss.<sup>10</sup> Collectively, poor cosmesis, few female-specific components, heavy prosthetic weight, combined with socket fitting challenges can lead to skin integrity concerns, pistoning, and unwanted noise. Although there is no gender difference in use of upper limb prostheses by individuals with congenital limb loss, 80% of females with acquired proximal amputations reject their prosthesis compared to 15% of males.<sup>11</sup>

There seem to be no differences across gender for intensity or frequency of residual limb pain or phantom limb pain. However, females with amputations tend to report greater pain, and that pain interferes with function to a greater extent than males.<sup>12</sup> This pain also interferes with activities of daily living including recreational and social activities, communication, self-care, and learning new skills.

Functional outcome is not impacted by gender in the same way it is affected by etiology, level of amputation or age as measured by the 2-minute walk test.<sup>13</sup> Although all individuals living with lower limb loss are at an increased risk of comorbidities such as osteoarthritis in proximal and contralateral joints, the risk of osteoarthritis among women with amputation is elevated 15% for each kg/m<sup>2</sup>.<sup>14</sup> This supports the need to address weight management, lower extremity strengthening, and activity modification in this specific demographic.

Another common pathology in women is osteoporosis. Of the 44 million diagnosed with or at risk for the disease, 68% are female, and 80 to 90% of all prosthetic users have a reduction of approximately 30% bone mineral density in their residual limb.<sup>15,16</sup> This is increased in females compared with males living with limb loss.<sup>16</sup> Thus, there is need

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to develop strategies to decrease the risk of loss of bone mineral density.

Pregnancy is another consideration for many women with amputations of traumatic etiology that are of reproductive, childbearing age. Pregnancy-related volume change weight gain may cause abnormal wear on components (e.g., prosthetic feet) that need to be monitored more frequently. Significant fluid and volume fluctuations of the residual limb are also more common in women particularly during pregnancy, and this can affect the fit of the prosthetic socket.<sup>17</sup> Additionally, weight fluctuation may necessitate a category change in selected componentry if, for instance, a component's weight limit is exceeded during gestation. Similarly, pregnancy will alter the woman's center of mass throughout the pregnancy, which may challenge balance, prosthetic alignment, and risk of falls for the prosthetic user. Appropriate monitoring and intervention should be applied if any of these complications arise; however, prevention of such issues is always the preferred strategy.

Transdisciplinary care teams including medical professionals that work with female Veterans with amputations should consider that enhanced levels of communication may be necessary in order to maximize satisfaction and quality of care. Women Veterans may also have a greater need for privacy and security in the clinic setting. Women Veterans with amputations will frequently have different rehabilitation goals, including a greater desire to become independent in household activities and to pursue different recreational and leisure pursuits.<sup>18</sup> Women who have undergone amputation also have different psychological and adjustment issues related to their amputation.<sup>18–20</sup> Providers caring for this group will be able to optimize health and quality of life if armed with awareness of key differences in gender as well as the latest scientific developments.

## **VA INITIATIVES AND STRATEGIES**

The VA increasingly recognizes the growing population and unique health care needs of women Veterans, including those who have limb amputations. VA implemented the Polytrauma System of Care and the Amputation System of Care (ASoC) to provide specialized expertise in rehabilitation and amputation care.<sup>21</sup> The ASoC incorporates the latest practices in medical rehabilitation, therapy services, and prosthetic technology in order to enhance the environment of care and ensure consistency in the delivery of rehabilitation services for all Veterans with amputations.

VA clinicians working with Veterans with amputations evaluate each patient individually and develop unique, patient-specific treatment plans that consider the Veteran's gender and other individual characteristics.<sup>22</sup> A transdisciplinary team including specialized physicians, prosthetists, and rehabilitation therapists utilizing a team-based approach helps to assure that each Veteran's short- and long-term goals and health care needs are addressed. To ensure that the psychosocial and emotional needs of the female Veteran

with an amputation are met, enhanced supportive services, including peer support mentoring or psychological counseling are provided.<sup>23</sup> Counseling or psychological support for other mental health issues such as post-traumatic stress disorder (PTSD) or military sexual trauma are also extended as needed.

Since implementing the ASoC in 2008, VA has completed and implemented numerous initiatives related to this group:

- Convening education and training conferences focused on women's health care needs;
- Conducting panel discussions with groups of Female Veterans with amputations;
- Hosting national conference calls including education for various groups of providers and care managers on the Veteran amputee population and specific considerations;
- Publishing scientific journal articles to educate providers on the unique needs of Female Veterans with amputations;<sup>18,24</sup> and
- Providing online educational training (FY2013) on the unique needs of female Veterans with traumatic extremity injury and amputation.

This review has provided an overview of considerations unique to the female Veteran with amputation. These factors should be taken into account if treatment strategies are to be successful and gaps in commercially available products and research are going to be appropriately identified. Logical next steps might include rigorously defining the population of women Veterans with amputation, systematically reviewing the literature regarding what is known about issues facing women Veterans with amputation, and generating associated research priorities. Still, much remains unknown and ongoing clinical and academic discourse on this topic is necessary to continue advancing the science and improving care for this deserving population.

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# Outcomes Associated With the Intrepid Dynamic Exoskeletal Orthosis (IDEO): A Systematic Review of the Literature

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**ABSTRACT** High-energy lower extremity trauma is a consequence of modern war and it is unclear if limb amputation or limb salvage enables greater recovery. To improve function in the injured extremity, a passive dynamic ankle-foot orthosis, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), was introduced with specialized return to run (RTR) therapy program. Recent research suggests, these interventions may improve function and return to duty rates. This systematic literature review sought to rate available evidence and formulate empirical evidence statements (EESs), regarding outcomes associated with IDEO utilization. PubMed, CINAHL, and Google Scholar were systematically searched for pertinent articles. Articles were screened and rated. EESs were formulated based upon data and conclusions from included studies. Twelve studies were identified and rated. Subjects ( $n = 487$ , 6 females, mean age 29.4 year) were studied following limb trauma and salvage. All included studies had high external validity, whereas internal validity was mixed because of reporting issues. Moderate evidence supported development of four EESs regarding IDEO use with specialized therapy. Following high-energy lower extremity trauma and limb salvage, use of IDEO with RTR therapy can enable return to duty, return to recreation and physical activity, and decrease pain in some high-functioning patients. In higher functioning patients following limb salvage or trauma, IDEO use improved agility, power and speed, compared with no-brace or conventional bracing alternatives.

## INTRODUCTION

The decision to amputate or attempt salvage of injured limbs is a subject of debate. This decision often emerges in the presence of high-energy lower extremity trauma (HELET).<sup>1,2</sup> An increase in HELET cases has resulted from conflicts related to Operations Iraqi Freedom (OIF), Enduring Freedom (OEF), and Operation New Dawn (OND) compared to previous conflicts.<sup>3,4</sup> This is because of improvements in body armor and battlefield trauma care, as well as changes in warfare style including enemy use of improvised explosive devices (IEDs).<sup>2,5–7</sup> Approximately 15,000 cases of extremity injury are associated with these conflicts, with 79% of all combat injuries resulting from blast exposure.<sup>2–4,7</sup> Further, approximately 1,600 amputations have occurred as a result of injuries sustained in these conflicts.<sup>3</sup>

Both limb amputation and salvage result in neuromusculoskeletal deficit, which can lead to pain and loss of strength, power generation, range of motion, and sensation. These impairments can impact function and quality of life. Outcomes following amputation have been compared to those following limb salvage.<sup>8</sup> A definitive advantage to either has not been identified.<sup>9–12</sup> Common goals of many injured service personnel include returning to an active lifestyle and possibly to active duty.<sup>1</sup> The high incidence of HELET and high functional expectations following rehabilitation has pressed the U.S. Departments of Defense (DoD) and Veteran's Affairs (VA) to create innovative adaptive devices and rehabilitation interventions.

One such device is the Intrepid Dynamic Exoskeletal Orthosis (IDEO). This energy storing and return—ankle-foot orthosis was first reported in 2009.<sup>13</sup> The IDEO was designed to address impairments created by HELET, such as diminished plantarflexion and propulsive force, decreased weight acceptance, and compromised joint stabilization.<sup>1,13,14</sup> Additionally, an integrated rehabilitation program Return to Run (RTR) in concert with prescription of an IDEO has shown promise in enabling military personnel to return to duty (RTD) and reintegrate into an active lifestyles following injury.<sup>1,15</sup> This orthosis also shows potential in managing other military- and combat-related conditions such as primary and traumatic arthritis.<sup>16</sup> Several studies have demonstrated efficacy in military service personnel after accommodation and use of the IDEO following HELET.<sup>17</sup> Therefore, the purpose of this systematic literature review was to rate the level of evidence and formulate empirical evidence statements (EESs) regarding outcomes associated with IDEO utilization.

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## PICO QUESTION

The PICO<sup>18</sup> (population, intervention, comparison, outcome) question guiding the search for evidence for this review was: In patients exposed to high-energy lower extremity trauma and limb salvage (P), what functional outcomes can be expected (O), following use of the IDEO (I) compared to alternatives such as conventional orthoses or amputation (C).

## METHODS

### Search Strategy

A search strategy used in several previous prosthetic and amputee systematic reviews was implemented.<sup>19,20</sup> The Medline and CINAHL databases were searched via the Ovid and EBSCO Host interfaces (respectively). Google Scholar was also searched. Searches were conducted on July 1, 2015, and were based on the following terms:

- Primary search terms: “ankle-foot orthosis, IDEO or Intrepid Dynamic Exoskeletal Orthosis, military, and limb salvage” (searched independently and in combination with 1 of the secondary search terms).
- Secondary search terms: “AFO, ankle brace, ground reaction, energy storing and return, running orthosis, patella tendon bearing orthosis, posterior strut orthosis, orthoses, orthotic, return to duty, return to run, lower extremity trauma, high activity, veteran, high energy lower extremity trauma, HELET, post-traumatic, lower limb impairment, integrated orthotic, integrated rehabilitation, integrated orthotic and rehabilitation, carbon fiber, limb reconstruction, and trauma.”

Searches were prelimited using the following criteria: English language, abstract available, and peer reviewed (CINAHL and Google Scholar). In Medline, the “map term to subject heading” feature was deselected to eliminate a medical subject heading (MeSH) term search. In CINAHL, a default Boolean search was used. A publication date of 2003–2015 was chosen in all databases as the beginning of OIF was in 2003. A manual search of included articles’ reference lists was also conducted in the event of very recent publications or keywords missed important publications in the automated search.

### Screening

Resulting references were exported to EndNote (vX7, Thompson, California) bibliographic citation software. Two reviewers independently screened resulting references’ titles, then abstracts, and finally, full-text articles according to inclusion/exclusion criteria (listed below). Articles were then classified as either (i) pertinent, (ii) not pertinent, or (iii) uncertain pertinence. Full-text articles were then reviewed for all manuscripts classified as pertinent or uncertain pertinence. Disagreements regarding citations of uncertain pertinence were resolved by having the 2 reviewers indepen-

dently review full-text articles then discussing and agreeing on ultimate inclusion or exclusion.

### Inclusion Criteria

- (1) Peer-reviewed publication;
- (2) Study used objective/quantifiable outcome measures;
- (3) IDEO was utilized as an intervention.

### Exclusion Criteria

- (1) Endoprosthetic ankle joints (i.e., joint arthroplasty);
- (2) Editorial, classification or taxonomy articles; and
- (3) Duplicate publication.

### Study Data

Data from each article including demographic, anthropometric, dependent and independent variables, quantifiable outcomes, and conclusions were entered into an Excel database (Microsoft Corporation, Redmond, Washington). These data were verified by a multidisciplinary team (i.e., physical therapists, orthotists, epidemiologists, and biomechanists) for completeness and accuracy. Data were assessed for the ability to aggregate for descriptive characteristics (i.e., anthropometrics) as well as outcomes (i.e., RTD rate, number of delayed amputations). Effect sizes (Cohen’s *d*), were calculated for all articles with available data using formulas based on independent *t* tests.<sup>21</sup> Controversy exists in the use of this technique compared with a calculation enabling control for data dependency. Effect sizes are commonly larger when data dependency is considered. However, limitations include requiring more information from source studies (i.e., correlation and coefficient between the data under examination).<sup>21</sup> Because the articles reviewed provided limited information, the calculation based on independent groups was selected recognizing that this is a conservative approach. Cohen described effect sizes as small (0.2), medium (0.5), and large (0.8).<sup>21</sup>

### Quality Assessment

The study design and methodological quality of those publications that met eligibility criteria were independently assessed by 2 reviewers according to the American Academy of Orthotists and Prosthetists (AAOP) State-of-the-Science Evidence Report Guideline Protocol.<sup>22</sup> Reviewers discussed pertinent issues until consensus on study design and methodological quality was obtained for the included publications. Each reviewer rated each study according to the AAOP Study Design Classification Scale that describes the type of study design.<sup>22</sup> The State of the Science Conference (SSC) Quality Assessment Form<sup>22</sup> was used to rate methodological quality of studies classified as experimental (E1–E5) or observational (O1–O6). The form identifies 18 potential threats to internal validity with the first 4 (E3–E5) or 5 (O1–O6) criteria not applicable for given study classifications and 8 potential threats to external validity. Threats were evaluated and tabulated.

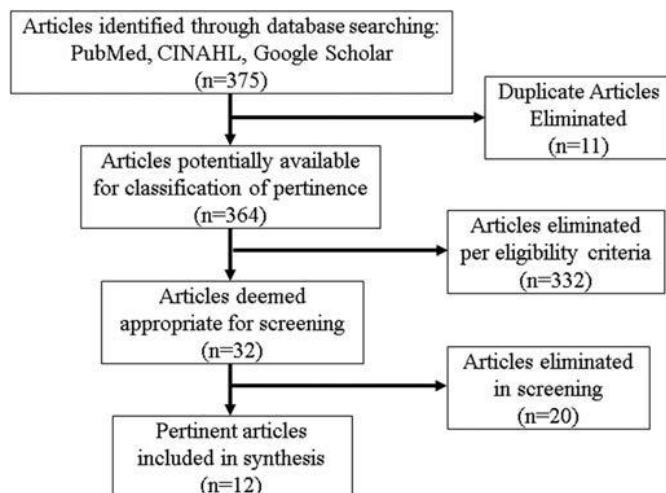
The internal and external validity of each study was then subjectively rated as “high,” “moderate,” or “low” based on the quantity and importance of threats present. As a guide, for internal validity, 0 to 3 threats was rated “high,” 4 to 6 threats as “moderate,” and 7 to 13/14 threats as “low.” For external validity, 0 to 2 threats was rated “high,” 3 to 5 threats as “moderate,” and 6 to 8 threats as “low.” Each study was given an overall quality of evidence of “high,” “moderate,” and “low” outlined by the AAOP State-of-the-Science Evidence Report Guidelines.<sup>22</sup> The overall ratings from the AAOP State-of-the-Science Evidence Report Guidelines were used in assigning confidence to the developed EESs described in the results section.

#### Empirical Evidence Statements

Based on results from the included publications, EESs were developed describing efficacy of the IDEO. Reviewers rated the level of confidence of each EES as “high,” “moderate,” “low,” or “insufficient,” based on the number of publications contributing to the statement, the methodological quality of those studies and whether the contributing findings were confirmatory or conflicting.<sup>22</sup>

## RESULTS

In total, 375 articles were identified from the search (Fig. 1). Of these, 12 met inclusion criteria. Publication dates of the 12 included articles ranged from 2011 to 2015 with 6 published in 2014. Half of the studies were observational and the other half was experimental (Table I). No systematic reviews or meta-analyses were identified. Because of heterogeneity in sample size and demography, methods, accommodation periods, outcome measures and design, and meta-analyses were not possible. Manuscripts were published predominantly in orthopedic trauma and biomechanical journals (Table II).



**FIGURE 1.** Results of the literature search and application.

**TABLE I.** Distribution of Included by Studies by Study Design

Study	Design Publications	
S1	Meta-Analysis	0
S2	Systematic Review	0
E1	Randomized Control Trial	1
E2	Controlled Trial	2
E3	Interrupted Time Series Trial	1
E4	Single Subject Trial	0
E5	Controlled Before and After Trial	2
O1	Cohort Study	2
O2	Case-Control Study	0
O3	Cross-Sectional Study	2
O4	Qualitative Study	1
O5	Case Series	0
O6	Case Study	1
X1	Group Consensus	0
X1	Expert Opinion	0
	Total	12

## Subjects

A total of 487 subjects were studied within all 12 manuscripts (Table III). Only six females were reportedly studied.<sup>14,16</sup> One subgroup of amputees ( $n = 57$ ) were included.<sup>23</sup> Uninjured, healthy subjects were recruited as controls in two studies to provide reference values of unimpaired gait function in which to compare against. This accounted for 25 subjects wherein both articles, reference groups' mean age was 23 years, mean height was 1.8 m, and the mean mass was 86 kg<sup>24</sup> and 87 kg<sup>25</sup> respectively. Conversely, control subjects ( $n = 81$ ), utilized in two other studies had experienced HELET including volumetric muscle loss below the knee, distal motor nerve injury, lower limb fracture, and other injuries.<sup>15,23</sup> Of these 81 control subjects, 31 had a mean age of 30 years and received IDEO only as opposed to IDEO and RTR training.<sup>15</sup> The remaining 50 of these subjects received limb salvage and there were no reports of IDEO provision nor anthropometry.<sup>23</sup>

Of the total 487 subjects from all included studies, another subgroup of 102 participants served as their own controls in

**TABLE II.** Distribution of the Studies per Journal

Journal	Number of Publications
<i>Clinical Biomechanics</i>	1
<i>Clinical Orthopaedics and Related Research</i>	2
<i>Gait and Posture</i>	1
<i>Journal of Biomechanical Engineering</i>	1
<i>Journal of Bone and Joint Surgery</i>	1
<i>Journal of Orthopaedic Trauma</i>	2
<i>Journal of Surgical Orthopaedic Advances</i>	1
<i>Journal of the American Academy of Orthopaedic Surgeons</i>	1
<i>Journal of Trauma and Acute Care Surgery</i>	1
<i>Journal of Trauma, Injury, Infection and Critical Care</i>	1
Total	12



**TABLE III.** Characteristics of Included Studies

Author (Year)	Study Design	Independent Variable(s)	Sample Size	Mean Age*	Outcome Measures	Overall Quality of Evidence
Patzkowski et al (2011)	O6	IDEO + RTR	1	29	Return to Recreation and Duty	Moderate
Owens et al (2011)	O4	IDEO + RTR	10	28.8	Return to Recreation and Duty	Moderate
Patzkowski et al (2012)	O3	IDEO + RTR	16	28	Return to Function, Recreation and Duty	Moderate
Patzkowski et al (2012)	O3	IDEO + RTR	17	31.4	RTD + Clinical Endpoints	Moderate
Patzkowski et al (2012)	E1	IDEO + RTR vs. Other Orthoses	18	31	Clinical Functional Performance Outcome Measures	Moderate
Harper et al (2014)	E5	IDEO Strut Stiffness	13	29.4	LE Biomechanical Analyses	High
Blair et al (2014)	O1	IDEO + RTR	146	31.5	Return to Duty	Moderate
Bedigrew et al (2014)	E2	IDEO + RTR. Early vs. Late Rehab Entry	84	NR†	Functional Performance Outcomes and Perceptive Measures	Moderate
Esposito et al (2014)	E3	IDEO Strut Stiffness	26	29.4	LE Biomechanical Analyses	Moderate
Harper et al (2014)	E5	IDEO Strut Construction	10	28.7	LE Biomechanical Analyses	High
Sheean et al (2014)	O1	Hindfoot Reconstruction (w/IDEO + RTR) vs. Amputation	122	26	Return to Function, Recreation and Duty	Moderate
Haight et al (2015)	E2	IDEO Strut Stiffness	24	29.3	LE Biomechanical Analyses	Moderate

IDEO, (Intrepid Dynamic Exoskeletal Orthosis; LE, Lower Extremity; NR, Not Reported; RTR, Return to Run. \*Experimental subjects and age in years. †Eligibility was aged >18 year.

repeated measure design protocols. They first completed preorthotic physical therapy. One group ( $n = 84$ ) underwent baseline assessment then received IDEO plus additional therapy followed by post-assessment.<sup>14</sup> This group included 5 females and was described in the manuscript better from an injury perspective than from a demographic perspective. The remaining 18 randomized for repeated assessment with three different orthoses including IDEO.<sup>26</sup>

Finally, a total of 253 of the 487 subjects were studied as experimental subjects. Eleven of the 12 studies reported age, and five<sup>24–28</sup> reported subject height and mass or body mass index (BMI). Interquartile mean (range) for studies reporting anthropometric data yields an age of 29.4 (1.7) years, height of 1.8(0.02) m, and mass of 87.8(1.9) kg. Mean BMI was 28.5 kg/m<sup>2</sup> reportedly.<sup>23</sup> Diagnoses for subjects in the experimental groups of studies included; open ankle fracture, knee, or ankle ligamentous damage or instability; bone, muscle, or other tissue loss; post-traumatic osteoarthritis; fractures of the spine and upper extremity; burns; hip subluxation; lower extremity motor nerve injury; ankle muscle weakness; neuropathy; paresis; equinovarus; shrapnel presence; vascular injury; ankle arthrodesis; reconstruction of the foot or ankle and soft tissue trauma. Additionally, subjects with spinal cord injury were provided IDEOs and physically assessed.<sup>14,15</sup> The mechanism of injury for these diagnoses tended to include HELET and more specifically causes such as motor vehicle accidents, blast injuries, gunshot wounds, and falls.

### Delayed Amputation and RTD

Seventy three patients initially requested amputation. Of these, 13 continued to request or received an amputation following provision of an IDEO and RTR training. Among

these, there were no reports of RTD.<sup>14,16,17,26</sup> Conversely, one study<sup>23</sup> reported that of 57 patients who received amputation, 7 (12.3%) RTD. Of 325 patients that received limb salvage, 108(33.2%) returned to duty. Within these 325 cases, one subset of 275 (84.6%) received an IDEO and a second subset of 244 (75.1%) reportedly received an IDEO in combination with RTR therapy. From the first subset, 96 (34.9%) returned to active duty, whereas 92 (37.7%) from the second subset returned to active duty.<sup>1,13,15–17,23</sup>

### Internal Validity

The most prevalent threats to internal validity in this body of literature include a lack of blinding, a lack of reporting exclusion criteria, no reported consideration for fatigue and learning, and no reporting of effect size (Table IV). The overall assessment was blended with 5/12 of the studies being rated as having low internal validity, 5/10 having moderate-level internal validity, and 2/10 having high internal validity. Additionally, two studies had attrition greater than 20% (22–38%).<sup>14,15</sup>

### External Validity

All 12 studies had high external validity. The most common threat to external validity across studies was a lack of describing the sample adequately. For instance, 7 of 12 studies did not adequately describe the sample in terms of anthropometry and demography.

### Effect Size

Effect sizes were unable to be calculated in several of the included studies. Five studies utilized either case report methodology or descriptive outcomes, which are not conducive to these calculations.<sup>1,13,15–17</sup> Additionally, Harper et al

**TABLE IV.** Internal and External Validity of Included Studies

Author (Year)	Study Design	Internal Validity																		External Validity									
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	Total	1	2	3	4	5	6	7	8	Total
Patzkowski (2011)	O6	n/a	n/a	n/a	n/a	n/a						•	•	•					•	Low	•	•	•	•	•	•	•	•	High
Owens (2011)	O4	n/a	n/a	n/a	n/a	n/a		•				•	•	•					•	Low	•	•	•	•	•	•	•	•	High
Patzkowski (2012)	O3	n/a	n/a	n/a	n/a	n/a		•	•			•	•	•					•	Low	•	•	•	•	•	•	•	•	High
Patzkowski (2012)	O3	n/a	n/a	n/a	n/a	n/a		•	•			•	•	•	•			•	•	Low	•	•	•	•	•	•	•	•	High
Patzkowski (2012)	E1	•		•	•	n/a		•	•			•	•	•	•		•	•	•	Moderate	•	•	•	•	•	•	•	•	High
Harper (2014)	E5	n/a	n/a	n/a	n/a	•		•	•	•	•	•	•	•	•		•	•	•	High	•	•	•	•	•	•	•	•	High
Blair (2014)	O1	n/a	n/a	n/a	n/a	n/a		•	•					•	•		•	•	•	Moderate	•	•	•	•	•	•	•	•	High
Esposito (2014)	E2	•				n/a		•	•	•	•	•	•	•	•		•	•	•	Moderate	•	•	•	•	•	•	•	•	High
Bedigrew (2014)	E3	n/a	n/a	n/a	n/a	•		•			•		•	•	•	•	•	•	•	Moderate	•	•	•	•	•	•	•	•	High
Harper (2014)	E5	n/a	n/a	n/a	n/a	•		•	•	•	•	•	•	•	•		•	•	•	High	•	•	•	•	•	•	•	•	High
Shecan (2014)	O1	n/a	n/a	n/a	n/a	n/a		•				•	•	•	•		•	•	•	Moderate	•	•	•	•	•	•	•	•	High
Haight (2015)	E2	•				n/a		•				•	•	•	•		•	•	•	Low	•	•	•	•	•	•	•	•	High

“n/a” indicates this particular criteria is not applicable for the given study design. The symbol “•” indicates that the criteria was satisfied. A blank space (no symbol) indicates that the particular criteria was not satisfied.

chose a graphic representation of spatiotemporal and bio-mechanical differences between carbon fiber and nominal stiffness IDEO braces.<sup>28</sup> This is an acceptable method for presenting measures of central tendency and variance and even preferred at times to depict continuous phenomena. However, this form of data presentation is also not conducive to the calculation of magnitude of effect.

Bedigrew et al compared differences in physical performance and perceptive measures at 3 assessment points; immediately postinjury, post physical therapy before bracing and again following bracing with additional physical therapy.<sup>14</sup> This group reported effect size (calculated as a difference in means) in all study measures. Effect sizes for differences in physical performance measures immediately postinjury compared to post bracing and therapy were considerable, ranging from 24 to 166% improvements. Effect sizes for pain scores were generally improved (i.e., reduced pain) following bracing and therapy by a magnitude of 23 to 35%. Patients entering into rehabilitation late experienced reduced magnitude of effect to 16 to 45% for physical performance and 27 to 38% for perceptive measures. Although these outcomes were of a relatively reduced effect compared to their early-entry peers, these were still statistically significant ( $p \leq 0.05$ ) as well as clinically important.

In total, 82 comparisons were eligible for effect size analysis per this review’s protocol. Of these, 64 involved use of an IDEO. More specifically, IDEO was compared relative to either a comparator (or no brace) or IDEO configuration (i.e., strut stiffness) was modified and compared. Within the subset of IDEO involved comparisons, 37.5% were of a large magnitude of effect, 25% were of medium magnitude, and the remaining 37.5% were of a small effect size.

For instance, Haight et al studied differences in IDEO strut stiffness between sound and involved limbs and to unimpaired control limbs.<sup>24</sup> Effect size (Cohen’s  $d$ ) was 0.03 (small) regarding peak knee extension moment between control and experimental subjects’ involved limb while using a compressive IDEO brace. Oppositely, effect size was 5.9 (large) when

comparing the differences in ankle range of motion between sound and involved sides when a stiff IDEO brace was utilized.

Esposito et al identified 5 statistically significant kinematic comparisons.<sup>25</sup> Of these, comparisons between compliant and more rigid IDEO strut designs were larger than those comparing nominal with stiff strut designs. Specifically, 3/3 kinematic comparisons were of medium effect size when comparing compliant with nominal and stiff IDEO struts, whereas 2/2 significant comparisons between nominal and stiff strut designs resulted in small effects.

During functional performance tasks, IDEO use resulted in large effects in self-selected walking velocity regardless of comparator and again had large effects on speed over uneven terrain and the 40-yd dash compared to a Blue Rocker orthosis (Allard USA, Rockaway, New Jersey). Medium effects were observed during stair climbing and in the four-square step test when IDEO was used in comparison with the Blue Rocker and a no brace condition.<sup>26</sup> When non-IDEO braces or no brace was used all significant comparisons were of a small magnitude of effect. Conversely, when IDEO was used during these tasks, 25% of significant comparisons were of a medium or large magnitude of effect.

#### Empirical Evidence Statements

The following four evidence statements were formulated and supported by moderate-level evidence:

- (1) In service personnel under 40 years of age, injured with high-energy lower extremity trauma, potentially confounded by post-traumatic ankle osteoarthritis, fitting, and use of IDEO with RTR physical therapy following limb salvage surgery may allow return to active duty for a limited population of high-functioning patients.<sup>1,13,15–17,23</sup>
- (2) In service personnel under 40 years of age, injured with high-energy lower extremity trauma, potentially confounded by post-traumatic ankle osteoarthritis,

fitting, and use of IDEO with RTR physical therapy following limb salvage surgery may allow return to exercise, recreation and physical activity, and decreased pain for a limited population of high-functioning patients.<sup>1,13,14,16,17,26</sup>

- (3) In service personnel under 40 years of age, injured with high-energy lower extremity trauma, fitting, and use of IDEO with RTR physical therapy following limb salvage surgery, results in improved agility, power, and speed, compared with no-brace or conventional bracing alternatives.<sup>26</sup>
- (4) IDEO strut stiffness should be considered with respect to patient preference.<sup>24,27-29</sup>

Evidence statements 1 and 2 are each supported by six moderate-quality studies. Evidence statement 3 is supported by a single moderate-quality study and statement 4 is supported by two high-quality studies and two moderate-quality studies. These combinations of evidentiary support provide a “moderate” level of confidence for each of the four EESs.

## DISCUSSION

With regard to study design, half of included studies were observational and half experimental. Although this is a reasonable blend of study designs, an optimal body of literature would enable meta-analysis from more prospective, randomized control trials. Internal validity could have been strengthened in these studies with minor reporting changes in accordance with standardized criteria.<sup>30,31</sup> For instance, had the included samples been better described (i.e., more uniform reporting of anthropometry and demography), effect sizes been reported and learning/accommodation and fatigue reported, more of the studies would have likely improved their internal validity ratings from “low” to “moderate” or “moderate” to “high.” Conversely, external validity was uniformly high which provides confidence that results have clinical importance but may be biased from a methodologic perspective (i.e., internal validity). Selection and reporting bias could contribute to favorable results in the included articles. Epidemiologic studies including larger samples could clarify the potential for larger generalizability to clinical practice.

Another strength of the included studies is that a blend of outcome measures supports the evidence statements and conclusions from these studies. Perceptive, functional performance, biomechanical, RTD, and delayed amputation outcomes have been studied. Although this is a strength and provides the ability to determine how the IDEO and RTR program may effect patients like those studied, it is unlikely that some of the outcomes selected would be valuable to others who may be able to utilize these interventions. For instance, older Veterans and civilians will not have comparable endpoints such as RTD. Many others such as biomechanical, functional, and perceptive measures will likely

translate across populations. The fact that the majority of the effect sizes were medium and large when IDEO and RTR therapy were provided suggests that the outcome measures selected were responsive to change and that these interventions had clinical significance in the studied populations.

As anticipated, all of the subjects studied were young ( $\leq 30$ -year mean) in accordance with a military population. With the exception of subjects diagnosed with post-traumatic osteoarthritis,<sup>16</sup> the majority were recently injured with acute HELET. A small number of female patients and some with spinal cord injury were included. However, there was insufficient representation to determine efficacy of IDEO and RTR in either of the latter groups. Further, the performance results described herein are largely attributed to IDEO and RTR (independent variables). However, it must be considered that a factor contributing to the effects observed include the prior fitness level and age of the subjects. It could be that the magnitude of effect would not be as large in patients who are older, have increased BMI and have lower levels of fitness. Moreover, the confounding effects of post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI) as it relates to prescription, utilization, and efficacy of IDEO and RTR remain unknown. As patients such as those studied begin to separate from military service and enroll for benefits with the Veterans Health Administration, it is unclear the extent to which these results will generalize to a larger Veteran population.

Approximately 3% of studied subjects requested or received an amputation despite provision of IDEO and RTR. None of this group returned to duty and the factors preventing their potential return were not reported.<sup>14,16,17,26</sup> Oppositely, approximately 12% of patients who went directly to amputation, did RTD.<sup>23</sup> It is unclear what differentiated the clinical decisions that lead each group to their respective endpoints. However, it is important to understand through future study, why limb salvage coupled with IDEO and RTR were not as successful in these cases. This further emphasizes the value of individual evaluations at the present time to determine the best clinical path for the individual patient. Approximately 33% of patients who received limb salvage, returned to duty. From these, approximately 80% received IDEO and RTR and approximately a third, returned to active duty.<sup>1,13,15-17,23</sup> A significant barrier in understanding this patient demographic and the associated clinical pathways they will follow, is the lack of an agreed upon definition for “limb-salvage” cases. Having such a definition would clarify which injuries are determined to be “salvageable” and what are the associated functional prognoses.

Major findings of this review include the EESs supported by moderate evidence suggesting that following HELET it is reasonable for a limited, homogeneous population within the military community, to be able to RTD.<sup>1,13,15-17,23</sup> Given the high costs and time associated with training for military service, this has obvious financial implications. Further, positive outcomes associated with post-traumatic interventions



such as IDEO and RTR may provide assurance with a decision to serve as opposed to a scenario where functional prognoses following HELET are only poor. Although the clinical endpoint of RTD is not applicable within the Veteran and civilian communities, return to high levels of function and recreation are.<sup>1,13,15–17,23</sup> Accidents resulting in lower limb trauma are prevalent outside of the military community accounting for nearly 250,000 hospitalizations per year in the private sector.<sup>32</sup> Therefore, adoption of IDEO and RTR interventions may likely have high clinical translation into the Veteran and private sectors. Under ideal circumstances, moderate evidence supports a return to high levels of function and recreation and decreased pain in accordance with these interventions.<sup>1,13,14,16,17</sup>

Another salient finding is that IDEO outperformed the Blue Rocker and Posterior Leaf Spring designs in functional tasks requiring multidirectional stepping, walking, and running on flat and uneven ground and stair climbing. Performance was also greater with IDEO than with a no brace condition. Confidence in this statement is also supported by moderate-level evidence. It is helpful to have comparative outcomes assessments to assist with clinical prescription of a device to maximize function with consideration for a certain patient demographic. Unfortunately, this body of literature only had a single comparative efficacy study.<sup>26</sup>

With regard to perceptive measures, moderate-level evidence also supports that IDEO strut stiffness was more of a factor with regard to patient preference than for gait quality.<sup>24,25,27,28</sup> Finally, pain is a concomitant issue following limb trauma. Use of IDEO was associated with decreased levels of pain.<sup>14</sup> Moderate-level evidence supports both of these effects associated with use of the IDEO. Included literature did not contain reports of safety incidents (i.e., breakage) or adverse events in association with use of the IDEO or RTR therapy and the only contraindication reported related to IDEO use was a knee range of motion of less than 90°. <sup>13</sup> The specific design elements of the IDEO that led to the reported outcomes were not clearly delineated. Therefore, it is unclear if design and construction differences will yield the same results. For instance, two specific IDEO designs are described: a modular rehabilitation device and a definitive device.<sup>13</sup> However, performance differences between these are not reported.

## LIMITATIONS

This body of literature only included two studies with high methodologic quality and one comparative efficacy study of multiple interventions. Additionally, the subjects studied were homogeneous. Therefore, generalizability beyond young, traumatically injured males is questionable. Methodologic quality could also be improved with standardized reporting.<sup>30,31</sup> Examples include more thorough sample descriptions and effect sizes. Additionally, incorporating blinding (i.e. raters, statisticians) would also improve internal validity.

## CONCLUSIONS

The IDEO was introduced to increase function and return to duty rates following lower extremity trauma and limb salvage. A return to run clinical rehabilitation pathway routinely accompanied the device. Twelve studies provide moderate evidence to support four empirical evidence statements. Briefly, following lower extremity trauma and limb salvage, use of IDEO with RTR therapy can enable return to duty, return to recreation and physical activity and decrease pain in some high functioning patients. Further, in higher functioning patients, the IDEO improved agility, power and speed, compared with no-brace or conventional non-custom bracing alternatives.

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# Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis

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**ABSTRACT** Advancements in ankle-foot orthotic devices, such as the Intrepid Dynamic Exoskeletal Orthosis (IDEO), are designed to improve function and reduce pain of the injured lower extremity. There is a paucity of research detailing the demographics, injury patterns and amputation outcomes of patients who have been prescribed an IDEO. The purpose of this study was to describe the demographics, presenting diagnosis and patterns of amputation in patients prescribed an IDEO at the Center for the Intrepid (CFI). The study population was comprised of 624 service members who were treated at the CFI and prescribed an IDEO between 2009 and 2014. Data were extracted from the Expeditionary Medical Encounter Database, Defense Manpower Data Center, Military Health System Data Repository, and CFI patient records for demographic and injury information as well as an amputation outcome. The most common injury category that received an IDEO prescription was injuries at or surrounding the ankle joint (25.0%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16.4%). Over 80% of the sample avoided amputation within a one year time period using this treatment modality. Future studies should longitudinally track IDEO users for a longer term to determine the long term viability of the device.

## INTRODUCTION

Improvement in U.S. military combat casualty care, coupled with advances in surgical techniques and improved body armor, has led to an increase in battlefield injury survival.<sup>1</sup> The “wounded-to-killed ratio,” which compares the number of wounded in action to the number who perished, currently stands at 7.4:1 for Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF).<sup>2</sup> Service members injured in these current conflicts have a survival rate that is higher than those injured in previous conflicts.<sup>3</sup> This increase in survival has led to a substantial increase in the number of service members who now struggle with long-term disability. In addition to battle injuries,

service members experience nonbattle injuries because of training activities, physical fitness training, as well as off-duty accidents which can result in long-term disability.<sup>4</sup>

Severe lower extremity injuries (LEI) make up the preponderance of combat-related injuries seen in service members injured within the OIF and OEF theatre of operations.<sup>5,6</sup> Data gleaned from the Joint Theatre Trauma Registry showed that severe LEI make up 65% of all injuries in both OIF and OEF theatre and 26% of these injuries involve a fracture, with over two thirds complicated by concomitant open wounds.<sup>1</sup> Not surprisingly, given the severity of many of these injuries, 10 to 15% of combat-related amputations occur after attempts at limb reconstruction and are considered late amputations, defined as occurring more than 90 days following the injury.<sup>1,7</sup> In a review of severe open tibia fractures (G&A type III) sustained in combat, 16.9% underwent early amputation whereas 5.2% underwent late amputation.<sup>8</sup> Those that went on to late amputation were more likely to require free or rotational flaps, had higher rates of deep soft tissue infection or osteomyelitis, and underwent more reoperations, all of which highlight the severity of these injuries and complicated post-limb reconstruction clinical course.<sup>9</sup>

Noncombat injuries can also result in severe and complex extremity injuries. When considering the impact of noncombat injuries, Hauret et al<sup>3</sup> reported that in 2009, injuries of the lower extremity made up 35% of all noncombat injury problems among military personnel; the most of any anatomical region. These overuse injuries were found to have a huge impact on mission readiness and deployment eligibility. The insurgence of LEI and resulting disabled service members (from both battle and nonbattle environments) have brought attention to the need for improving the rehabilitative care in the Department of Defense.

The Center for the Intrepid (CFI), along with two other Department of Defense Advanced Rehabilitation Centers, strives to recuperate injured Soldiers back to duty or civilian life. An

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advanced ankle-foot orthotic (AFO) device, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), was developed at the CFI. The IDEO offers an alternative treatment modality to conventional AFOs and increases function of the injured limb allowing patients to achieve relatively high levels of mobility while simultaneously reducing pain levels.<sup>10</sup> When compared to traditional, commercially available AFOs to include the posterior leaf spring and Blue Rocker (Allard, Rockaway, New Jersey), patients performed significantly better in all validated physical performances measures when using the IDEO. The IDEO has been shown to improve the functional capabilities of the LEI population when accompanied with a comprehensive return to run (RTR) clinical pathway.<sup>11</sup> For instance, a cohort of patients prescribed an IDEO were found to have improved outcomes in the domains of running, cycling, and self-reported decreased amounts of pain.<sup>10,11</sup> The combination of the IDEO and RTR pathway has been shown to change a patient's decision to amputate and instead continue with their salvaged limb using the IDEO.<sup>12</sup>

Although the benefits of the IDEO device have been characterized in the fields of biomechanics and recreational activity<sup>11,13</sup>, there is a paucity of research detailing the descriptive characteristics and injury patterns of the patients who have been prescribed an IDEO. Moreover, little information exists quantifying the percentage of patients that have undergone amputation after being prescribed an IDEO and completing the RTR program. Therefore, the purpose of this descriptive epidemiologic study was to comprehensively detail demographic and occupational characteristics of those who use an IDEO, categorize the presenting injury, and quantify the proportion of patients who underwent amputation after IDEO prescription. The overarching study aims were to: (1) comprehensively describe the demographic and service characteristics of the CFI patient population who used an IDEO and (2) identify IDEO prescription patterns and rates of amputation. This research was the first step in creating an injury profile of patients who will benefit most from an IDEO and the subsequent rehabilitation. Creating such an injury profile will provide clinicians information on which patients can benefit the most from the IDEO and the RTR training program.

## MATERIALS AND METHODS

The population under study included all injured service members who were treated at the CFI during the period 2009–2014. Data were extracted from the Expeditionary Medical Encounter Database (EMED), Defense Manpower Data Center (DMDC), Military Health System Data Repository (MDR), and the CFI patient records. An analytic dataset was constructed with variables representing the most current status on demographic and military characteristics. Injured service members who were prescribed an IDEO at the CFI were identified and corresponding administrative and medical records were merged to form the final analytical dataset. The demographic descriptions were: sex (M/F), age (<20, 20–25, 26–30, and >30 years), race (White, Black, Asian, American Indian/Alaskan Native, Hawaiian/Other Pacific Islander, and Other), and marital status (married, divorced/separated). Military characteristics were: service (Army,

Marines, Air Force, and Navy/Coast Guard/NOAA) and length of service (1–5, 6–10, 11–20, and 20+ years).

Data elements such as initial referral diagnosis and date of first visit were collected at CFI from February 2009 to November 2014 for all patients who were referred for an IDEO. Initial referral diagnosis was the primary diagnosis that was the cause of the IDEO referral to the CFI. Because of the absence of a systematic method to record the referral diagnoses, this information was collected in a disparate manner. To categorize these data, subject-matter experts (a fellowship-trained orthopedic trauma surgeon and a senior rehabilitative clinician) assigned the primary referral diagnoses into seven injury types: (1) nerve injury below knee; (2) tibia (excluding pilon fracture); (3) ankle ([pilon fracture, ankle post-traumatic osteoarthritis [PTOA], and ankle fusion); (4) hindfoot (hindfoot PTOA, fusion); (5) midfoot/forefoot; (6) soft tissue (compartment syndrome, Achilles tendon injury, and quadriceps injuries); and (7) other. For data quality assurance, a random 10% of referral diagnoses were compared with the electronic military medical record system by a qualified clinician.

An amputation of the lower extremity was identified if one of the diagnosis codes (see Appendix A) or procedure codes (see Appendix B) was found after at least 22 days from the date of initial evaluation. Procedure codes for fitting a prosthesis were taken into consideration only when found in consortium with an ICD-9 (International Classification of Diseases, 9th

**TABLE I.** Demographic Characteristics and Amputation Status of Service Members Prescribed IDEO (*N* = 624), 2009–2014

Demographic Characteristic		Total <sup>a</sup> <i>N</i> = 624, <i>n</i> (%)	Amputation <sup>a</sup> <i>N</i> = 121, <i>n</i> (%)
Sex	Male	573 (91.8)	120 (99.2)
	Female	28 (4.5)	1 (<1)
Age (Years)	<20	5 (<1)	2 (1.6)
	20–25	121 (19.4)	31 (25.6)
	26–30	119 (19.1)	23 (19.0)
	>30	313 (50.2)	52 (43.0)
Race	White	439 (70.3)	94 (77.7)
	Black	64 (10.2)	10 (8.3)
	Asian	32 (5.1)	7 (5.8)
	American Indian/ Alaskan Native	4 (<1)	2 (1.6)
	Hawaiian/Other Pacific Islander	4 (<1)	2 (1.6)
	Married	414 (66.3)	89 (73.5)
	Divorced/Separated/ Single	178 (28.5)	32 (26.4)
Service	Army	423 (67.8)	80 (66.1)
	Marines	97 (15.5)	32 (26.4)
	Air Force	46 (7.4)	5 (4.1)
	Navy/Coast Guard/ NOAA	37 (5.9)	4 (3.3)
Length of Service (Years)	1–5	95 (15.2)	21 (17.3)
	6–10	171 (27.4)	46 (38.0)
	11–20	169 (27.1)	34 (28.1)
	>20	94 (15.1)	11 (9.1)

<sup>a</sup>Subject numbers for each variable do not add to total sample due to missing data.

**TABLE II.** Referring Injury Diagnosis Categories, *N* = 533

Injury Type	Description	<i>n</i> (%)
Ankle	Pilon fractures, PTOA, fusion	139 (25.0)
Tibia	Fractures, excludes pilon fractures	96 (17.5)
Nerve injury; below knee	Functional deficit below knee	91 (16.4)
Hindfoot	PTOA, fusion	79 (14.2)
Soft tissue	Compartment syndrome, Achilles tendon injuries, quadriceps injuries	33 (5.9)
Midfoot/Forefoot	Foot pain, forefoot/midfoot PTOA, toe amputation	21 (3.8)
Other	Osteomyelitis, late effects of fracture, nerve injury above knee	93 (17.4)

PTOA, post-traumatic osteoarthritis.

Revision, Clinical Modification) or procedure code for a lower extremity amputation.

## RESULTS

The study population comprised 624 service members who were treated at the CFI and prescribed an IDEO between 2009 and 2014. The demographics of the population are documented in Table I. The majority of the service members were equally divided above and below 30 years of age (50.2%), male (91.8%), married (66.3%), and white (70.3%). In comparison with the overall Armed Services,<sup>2</sup> this sample is slightly older, more likely to be male and married but similar in race/ethnicity. The study cohort predominately consisted of Army (67.8%) service members, followed by the Marine Corps (15.5%). This is consistent with the U.S. military population.<sup>2</sup> The majority of the population had a length of service between 6 and 10 years (27.4%), closely followed by 11 to 20 years (27.1%).

The description and distribution of the referring injury diagnoses are outlined in Table II. Of the 624 service members prescribed an IDEO, 533 (85.4%) had a clear presenting diagnosis documented in the medical record and of these, 38 (7.1%) had a bilateral diagnosis. The most common injury category that received an IDEO prescription was of injuries at or surrounding the ankle joint (25.0%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16.4%).

Less than 20% (*n* = 121) of the study sample underwent a delayed amputation during the study period. Figure 1 displays the percentage of service members prescribed an IDEO in each injury diagnosis category who later underwent delayed amputa-

tion of the injured extremity. Service members with diagnoses in the categories of midfoot/forefoot injuries (28.6%), soft tissue injuries (27.3%), and hindfoot injuries (26.6%) experienced the highest proportion of amputation after IDEO prescription. Those with ankle joint injuries (13.7%) and nerve injuries below the knee (14.3%) demonstrated the lowest rates of amputation. The majority of the delayed amputations (*n* = 64 [53.8%]) occurred within 3 months after referral for an IDEO with 84% occurring within the first year.

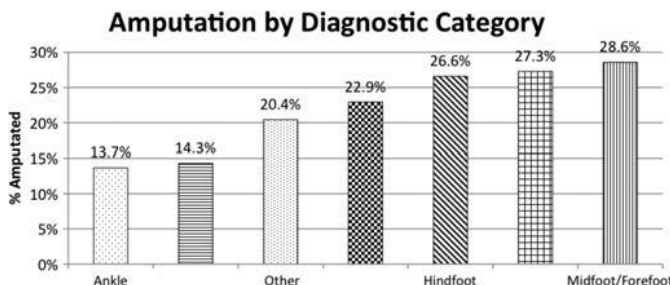
## DISCUSSION

After over a decade of military conflicts in Iraq and Afghanistan and improvements in combat casualty care and body armor, the focus of care of the wounded service member is shifting from acute care to improving the quality of life for those with long-term disability.<sup>14</sup> To adequately care for all injured service members, a careful evaluation of current rehabilitative treatments is necessary. This study provides information on the demographics, injury profile, and delayed amputation rates of service members who have been prescribed an IDEO at the CFI after severe LEI. It is an important step toward identifying which injuries are most appropriately treated by this type of lower extremity bracing.

When examining the IDEO prescription patterns, an injury involving the ankle joint, including pilon fractures, ankle fusions, and PTOA, was the most frequently reported primary diagnosis (25%), followed by injury to the tibia (17%) and a nerve injury below the knee (16%). Considering nearly 58% of the injuries were at or could influence the functioning of the ankle joint, these groupings are consistent with the mechanism of action of the IDEO, which is designed to provide support as well as energy storage for the ankle joint during gait and other high-level activities.<sup>11</sup>

Less than 20% of the study sample underwent an amputation during the study period. In a prospective observational study of IDEO users completing the RTR clinical pathway, 82% of patients who were initially considering amputation at the start of the program favored limb salvage after receiving an IDEO and completing the RTR program.<sup>12</sup> When examining the individual diagnostic categories of the present study, 29% of midfoot/forefoot injuries, 27% of soft tissue injuries, and 27% of hindfoot injuries required eventual amputations, whereas the lowest rates of amputation were of nerve injuries below the knee (14%) as well as injuries of ankle (14%). These results are consistent with the categories in published disability data following combat-related injuries.<sup>15</sup>

With the high prevalence of battle and nonbattle-related serious extremity injuries in our service members,<sup>4-6</sup> it is important to examine the efficacy of treatment modalities for rehabilitative care. This descriptive study is a first step in identifying injured patients who may benefit the most from an IDEO prescription in terms of both rehabilitation and reducing the likelihood of amputation. Further research is necessary to fully understand this profile. Once an injury profile is identified, injured service members can benefit from having an IDEO prescribed earlier in the rehabilitative process and thus facilitate a more timely recovery of function. In addition, by understanding who will benefit most from an IDEO, resources that are currently allocated for the unnecessary use of the IDEO could be redirected

**FIGURE 1.** Proportion of amputations by diagnostic category.

for other treatment options. This injury profile should not take the place of clinical decision-making but rather enhance the current knowledge base and help to inform both clinicians and service members as decisions on care are made.

One of the limitations of this study is the potential for selection bias since the study sample was one of convenience and included only service members who were prescribed an IDEO at the CFI. In addition, a clear presenting diagnosis was documented in only 85% of the total study sample and acute diagnoses, side of injury, or mechanism of injury (including combat or noncombat) was not available for the majority of the sample. Since the side of injury is unknown, it is possible that the lower extremity with an amputation was opposite to the lower extremity with the IDEO prescription. The amputation rate would be an overestimation if this occurred. Although a functional benefit to the use of the IDEO compared to other AFOs has been demonstrated,<sup>11</sup> the number of patients who benefited from the IDEO from a functional rehabilitation standpoint is unknown. This study reports IDEO prescription but cannot determine the extent to which the treatment may have been efficacious. In addition, the current study suffers from some small sample sizes in the diagnostic groups. Although the midfoot/forefoot had the highest proportion of amputations, one or two individuals having an amputation in another diagnostic group could shift that percentage significantly. It will be beneficial for future studies to estimate the weighted amputation probability for each diagnosis group.

Although a presenting diagnosis was not available for the entire study sample, a qualified clinician from the armed forces validated a random 10% of the referral diagnosis with electronic military medical record system. The validation process provided data quality assurance to the diagnostic category data element, which was a key component of the analysis. A strength of the study was that multiple datasets were able to be merged to include primary data and secondary data. The primary dataset identified the study sample and presenting diagnosis whereas secondary datasets provided access to a large volume of medical data for validation and augmentation of primary data.

This is the first study to comprehensively examine the demographics, referral diagnoses, and amputation outcomes of a sample of service members prescribed the IDEO to facilitate function of an injured lower extremity. The majority of the service members had a presenting diagnosis at or near the ankle, and can potentially benefit from an AFO designed to support the joint and augment some of the lost ankle function. Twenty percent of the sample underwent eventual amputation during the year following initial IDEO prescription. This study is a first step in categorizing primary injuries that may benefit from IDEO prescription and determining which injuries undergo delayed amputation at higher rates. Longitudinal tracking of IDEO users and identification of functional outcomes will provide additional information on the efficacy of this device for rehabilitation after an LEI.

## APPENDIX A

### ICD-9 Codes for Amputations

89600	89620	89700
89610	89630	89710

89720	89760	V4975
89730	89770	V4976
89740	V4973	V4977
89750	V4974	

## APPENDIX B

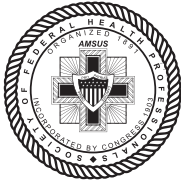
### Procedure Codes for Amputation

8410	8414	8417	8446
8412	8415	8440	8447
8413	8416	8445	8448

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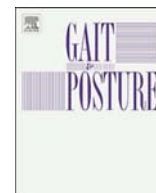


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## Full length article

How humans use visual optic flow to regulate stepping during walking<sup>☆</sup>Mandy M. Salinas<sup>a</sup>, Jason M. Wilken<sup>b</sup>, Jonathan B. Dingwell<sup>a,\*</sup><sup>a</sup> Department of Kinesiology & Health Education, University of Texas, Austin, TX 78712, USA<sup>b</sup> Center for the Intrepid, Brooke Army Medical Center, JBSA Ft. Sam Houston, TX, USA

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## ABSTRACT

Humans use visual optic flow to regulate average walking speed. Among many possible strategies available, healthy humans walking on motorized treadmills allow fluctuations in stride length ( $L_n$ ) and stride time ( $T_n$ ) to persist across multiple consecutive strides, but rapidly correct deviations in stride speed ( $S_n = L_n/T_n$ ) at each successive stride,  $n$ . Several experiments verified this stepping strategy when participants walked with no optic flow. This study determined how removing or systematically altering optic flow influenced peoples' stride-to-stride stepping control strategies. Participants walked on a treadmill with a virtual reality (VR) scene projected onto a 3 m tall, 180° semi-cylindrical screen in front of the treadmill. Five conditions were tested: blank screen ("BLANK"), static scene ("STATIC"), or moving scene with optic flow speed slower than ("SLOW"), matched to ("MATCH"), or faster than ("FAST") walking speed. Participants took shorter and faster strides and demonstrated increased stepping variability during the BLANK condition compared to the other conditions. Thus, when visual information was removed, individuals appeared to walk more cautiously. Optic flow influenced both how quickly humans corrected stride speed deviations and how successful they were at enacting this strategy to try to maintain approximately constant speed at each stride. These results were consistent with Weber's law: healthy adults more-rapidly corrected stride speed deviations in a no optic flow condition (the lower intensity stimuli) compared to contexts with non-zero optic flow. These results demonstrate how the temporal characteristics of optic flow influence ability to correct speed fluctuations during walking.

## 1. Introduction

During forward motion, spatiotemporal information is projected onto the retina by the objects and surfaces in our environment. The relative motions between ourselves and these external objects and surfaces produce visual optic flow. These optic flow patterns are used to guide locomotion. Uniquely, however, our movements through our environment also alter the optic flow pattern [1]. Visual optic flow plays a central role in human balance and locomotor control particularly during navigation in complex environments [2] and provides a continuous stream of information used to distinguish steering direction [3,4], and ground distance traveled [5]. Therefore, to gain a better understanding of navigation in complex environments, it is essential to investigate how visual optic flow influences how humans regulate walking.

When walking on a treadmill in a static environment that provides no optic flow, young healthy adults naturally try to maintain approximately constant stride speed ( $S_n$ ) at each successive stride,  $n$  [6–8]. They do this by explicitly exploiting the inherent redundancy between

stride length ( $L_n$ ) and stride time ( $T_n$ ). Participants allow deviations in  $L_n$  and  $T_n$  relative to their mean values to persist across multiple consecutive strides, while rapidly correcting any deviations in  $S_n$ . Humans adopt this active speed correction in spite of there being many other very different, but equally feasible stepping strategies available to them [6,7]. These findings were independently verified in other studies [9,10]. Considering it is well-documented that humans use optic flow to regulate the speed of locomotion [11–15], particularly in the short-term [16], this study explored how systematically manipulating optic flow would impact (if at all) how healthy adults modified their stride-to-stride stepping strategies (especially active speed correction) during treadmill walking.

To truly gain insight to the impact of these systematic manipulations during walking, we consider how humans perceive change in a given stimulus. When walking overground, small stride-to-stride changes in walking speed [17] induce small changes in the nominal optic flow rate. Conversely, when walking on most treadmills, the nominal optic flow rate will be approximately zero, so any small change in walking speed (relative to the treadmill belt speed) will immediately induce some non-

<sup>☆</sup> The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defense or the U.S. Government.

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zero optic flow that will indicate the person is now moving relative to their surrounding environment. This suggests that it may be easier for humans to adopt active speed correction in such contexts, given their natural reliance on visual optic flow. Indeed, Weber's law states that humans' ability to detect small changes in sensation intensity depend on the original intensity [19]: the greater the original intensity, the harder it is to detect small changes. In walking, any small change in speed that might occur on any given stride would induce a corresponding change in optic flow. Weber's law implies that these would be easier to detect when the nominal optic flow was zero (no optic flow), and should scale as the relative rate of optic flow is varied. Here, we hypothesized that participants would more-rapidly correct stride speed deviations in a no optic flow context compared to contexts with non-zero optic flow and these stride-speed corrections would scale as relative optic flow speed was varied, consistent with Weber's Law. Additionally, if visual information (optic flow, motion parallax) is removed, by introducing a completely uniform stimulus, this creates a sensory deprivation known as the Ganzfeld effect [22]. We hypothesized that introducing such a stimulus would affect stride-to-stride regulation of walking in a significant manner.

This study therefore determined how humans altered stride-to-stride control of their stepping movements when optic flow was removed and/or systematically manipulated in a virtual environment. By removing and systematically manipulating optic flow within the same treadmill context, this study sought to demonstrate that any differences found in stride-to-stride stepping control strategies would be due to these particular experimental manipulations. We hypothesized that: (1) when walking with static visual information but *no* optic flow, participants would tightly regulate stride-to-stride fluctuations in speed ( $S_n$ ), consistent with previous findings during treadmill walking [6,8–10], (2) when walking with *non-zero* optic flow, participants would regulate fluctuations in  $S_n$  less tightly and in a manner consistent with Weber's law, and (3) that removal of visual information altogether (both moving and static) would significantly disrupt stride-to-stride regulation of walking, as observed in the “Ganzfeld effect” [18].

## 2. Methods

Twenty healthy young adults (10 Female /10 Male,  $25.7 \pm 4.7$  years) participated. All participants were screened to ensure they had no prior history of lower limb injuries, surgeries, or cardiovascular, respiratory, neurological, musculoskeletal or visual conditions that might have affected their gait. This study was approved by Institutional Review Board at The University of Texas at Austin and all participants provided written informed consent prior to participation.

All participants walked on an instrumented “V-Gait” treadmill (Motekforce Link, Amsterdam, Netherlands; Fig. 1A) while wearing a safety harness (Petzl, Crolles, France). The V-Gait system consists of an instrumented dual-belt treadmill ( $1\text{ m} \times 2\text{ m}$ ) and a VR scene projected onto a 3 m tall 180° semi-cylindrical screen in front of the treadmill (Fig. 1A). An integrated 10-camera Vicon motion capture system (Oxford Metrics, Oxford, UK) was used to record movement kinematics.

For all trials, the treadmill was set to operate a constant belt speed, non-dimensionally scaled to each participant's own leg length,  $v_w = \sqrt{Fr \cdot g \cdot l}$ , where  $Fr = 0.16$  is the Froude number,  $g = 9.81\text{ m/s}^2$ , and  $l$  is leg length in meters, measured from the greater trochanter to the floor [8,19,20].

Participants completed a 5-min warm-up followed by two 5-min trials at each of five experimental conditions: blank screen (“BLANK”:  $v_{flow} = 0$ ), static VR scene (“STATIC”:  $v_{flow} = 0$ ), optic flow speed slower than walking speed (“SLOW”:  $v_{flow} = \frac{1}{3} \times v_w$ ), optic flow speed matched to walking speed (“MATCH”:  $v_{flow} = v_w$ ), and optic flow speed faster than walking speed (“FAST”:  $v_{flow} = 3 \times v_w$ ). Experimental conditions were presented in random order to each participant, with presentation order balanced across participants.

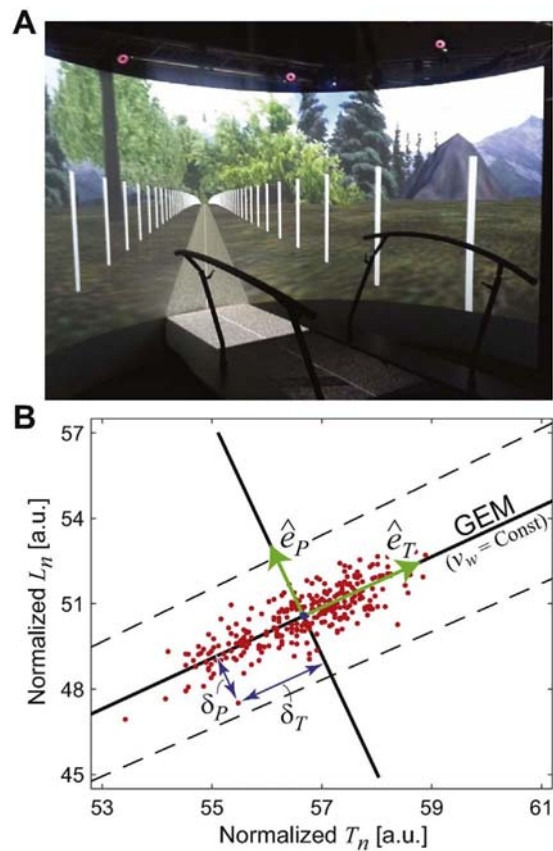


Fig. 1. Walking Environment and Task Goal Definition.

(A) Photograph of the V-Gait system (Motekforce Link, Amsterdam, Netherlands) used. The V-Gait consisted of an instrumented dual-belt treadmill and virtual reality (VR) scene projected onto a 180° screen in front of the treadmill. The VR scene depicted a path through a forest with mountains in the background and was used for 4 of the 5 experimental conditions. The virtual path was lined with white posts spaced every 3 m to increase motion parallax [3,23]. In the 5<sup>th</sup> BLANK condition, this scene was not displayed, and instead only a pure white screen was projected. (B) Schematic of the Goal Equivalent Manifold (GEM) for Constant-Speed Walking. Example stride time ( $T_n$ ) and stride length ( $L_n$ ) data, where each dot represents an individual stride  $n$ . The solid diagonal line represents all the combinations of  $[T_n, L_n]$  that achieve the exact same treadmill belt speed  $v_w$ . This line defines the constant-speed GEM. Orthonormal basis vectors  $[e_T, e_P]$  were defined, aligned tangent to and perpendicular to the GEM, respectively. Time series of  $L_n$  and  $T_n$  were transformed into  $\delta_T$  and  $\delta_P$  time series of deviations in the  $e_T$  and  $e_P$  directions, respectively, relative to the preferred operating point,  $[T^*, L^*]$  (POP).

Participants were instructed only to “walk and look straight ahead.” Participants did not hold onto the treadmill handrails during any walking trial. During the “BLANK” condition, to keep participants’ focus on the screen and to minimize looking down at their feet, participants wore goggles (Uvex, Smithfield, RI), modified to block the lower most portion of their visual field of view. Full frontal and peripheral vision remained unobstructed.

Kinematic data were recorded at 120 Hz using a previously validated whole-body 57-marker set [21]. However, for the analyses conducted here, we used marker data from only the feet and pelvis. Raw kinematic data were processed using Vicon Nexus software (Oxford Metrics, Oxford, UK). Additional data reduction and analyses were performed using MATLAB (MathWorks, Inc., Natick, MA).

The primary objective of walking is to move a finite distance in a finite time. Thus, the variables stride length ( $L_n$ ), stride time ( $T_n$ ) were chosen as the primary variables of interest. Individual heel strikes were determined by finding the local maxima of the distances between the pelvis and heel markers in the anterior-posterior direction [22]. A stride was defined as the period between a right heel strike to the next right heel strike. Stride length ( $L_n$ ) was calculated as the anterior-posterior displacement between two consecutive right heel strikes and using the

heel marker data. Stride time ( $T_n$ ) was calculated as the time between two consecutive right heel strikes. These data were used to extract time series of stride lengths ( $L_n$ ), stride times ( $T_n$ ), from which time series of stride speeds were then also computed ( $S_n = L_n/T_n$ ).

In the task of walking on a treadmill at constant belt speed,  $v_w$ , the primary requirement is to not walk off the treadmill [6]. There are many combination of  $L_n$  and  $T_n$  that satisfy this inequality and will successfully accomplish this task, expressed as follows:

$$-\frac{L_{TM}}{2} < \sum_{n=1}^N (L_n - v_w T_n) < \frac{L_{TM}}{2}, \quad (1)$$

where  $L_{TM}$  is the length of the treadmill and  $v_w$  is the treadmill belt speed. Although there are many strategies to achieve this [6,7], one simple strategy is to try to maintain constant speed at each stride, and can be mathematically written as the following goal function:

$$L_n - v_w T_n = 0 \rightarrow \frac{L_n}{T_n} = v_w, \quad (2)$$

This goal function is one *possible* movement strategy and can be depicted as a diagonal line representing all the potential  $L_n$  and  $T_n$  combinations that would yield constant belt speed  $v_w$  (Fig. 1B). This line represents the goal equivalent manifold (GEM). We then used the procedures developed in [6] to decompose these data into two new variables, tangent to ( $\delta_T$ ) and perpendicular to ( $\delta_P$ ) the speed GEM. First,  $T_n$  and  $L_n$  were normalized to unit variance by dividing by their own standard deviations. Then, a preferred operating point (POP) was defined as  $[T^*, L^*] = [\bar{T}, \bar{L}]$ , and the new coordinate system was centered at this point,  $T'_n = T_n - T^*$  and  $L'_n = L_n - L^*$ . Lastly, the following coordinate transformation was performed to acquire deviations tangent ( $\delta_T$ ) and perpendicular to the speed GEM ( $\delta_P$ ) (Fig. 1B).

$$\begin{bmatrix} \delta_T \\ \delta_P \end{bmatrix} = \frac{1}{\sqrt{1 + v_w^2}} \begin{bmatrix} 1 & v_w \\ -v_w & 1 \end{bmatrix} \begin{bmatrix} T'_n \\ L'_n \end{bmatrix}, \quad (3)$$

As tangent deviations do not affect walking speed, they are considered “goal-irrelevant”. Alternatively, perpendicular deviations ( $\delta_P$ ) directly affect walking speed, and are thus considered “goal-relevant” (Fig. 1B).

Considering the primary task requirement, the time series of absolute position ( $P_n$ ) on the treadmill at each stride  $n$  was also examined and determined from  $L_n$  and  $T_n$ , as follows:

$$P_n = \sum_{k=1}^n (\Delta P_k) = \sum_{k=1}^n (L_k - v_w T_k). \quad (4)$$

This measure was computed from the stepping variables ( $L_n$ ,  $T_n$ ) to analyze  $P_n$  deviations on a stride-to-stride basis and to be consistent with the other time series stepping variables.

For each trial, we computed means and standard deviations ( $\sigma$ ) for each of these time series ( $T_n$ ,  $L_n$ ,  $S_n$ ,  $P_n$ ,  $\delta_T$ ,  $\delta_P$ ). We also used Detrended Fluctuation Analysis (DFA) [23–26] to quantify the stride-to-stride fluctuation dynamics and to determine the extent of control for each variable, as we did previously [6]. DFA scaling exponents,  $\alpha$ , quantify the statistical persistence or anti-persistence in a scalar time series, independent of the magnitude of variability. Scaling exponents  $\alpha > 1/2$  indicate statistical *persistence*: deviations in one direction are more likely to be followed by deviations in the same direction. Scaling exponents  $\alpha < 1/2$  imply *anti-persistence*: deviations in one direction are more likely to be followed by deviations in the opposite direction (reversals). Scaling exponents  $\alpha = 1/2$  indicate no correlation: all deviations are equally likely to be followed by deviations in either direction. In the context of control, variables that are *not* tightly controlled generally exhibit strong statistical persistence ( $\alpha > 1/2$ ), while variables that *are* tightly controlled generally exhibit either uncorrelated or anti-persistent fluctuations ( $\alpha \leq 1/2$ ) [6,7,27]. Thus, while standard deviations ( $\sigma$ ) captured the average magnitude of fluctuations in these time series, these DFA exponents ( $\alpha$ ) captured

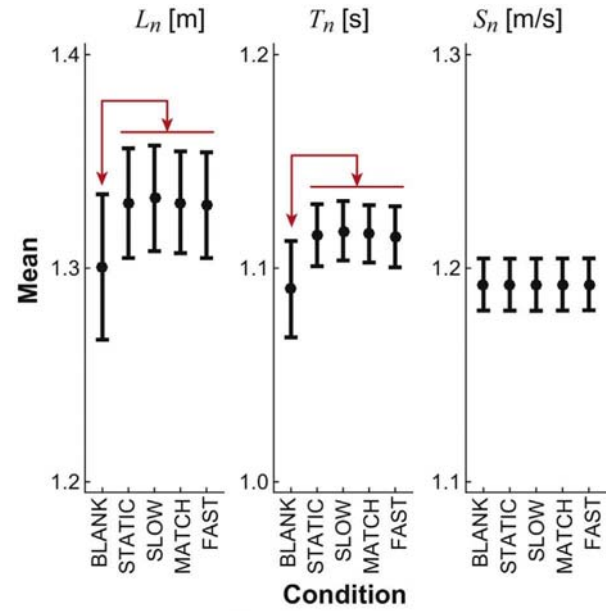


Fig. 2. Means of Stride Parameters.

Stride lengths ( $L_n$ ), stride times ( $T_n$ ), and stride speeds ( $S_n = L_n/T_n$ ). In each sub-plot, data shown are for the five different optic flow conditions: blank screen (BLANK), static VR scene (STATIC), or VR scene with optic flow speed either slower than (SLOW), matched to (MATCH), or faster than (FAST) walking speed. Error bars represent between-participant  $\pm 95\%$  confidence intervals. Red arrows/lines indicate statistically significant differences between conditions. In the BLANK condition, participants adopted shorter stride lengths ( $L_n$ ) and faster stride times ( $T_n$ ) compared to all other experimental conditions (STATIC, SLOW, MATCH, and FAST).

how quickly participants actively *corrected* these fluctuations on subsequent strides (i.e. stride-to-stride strategy).

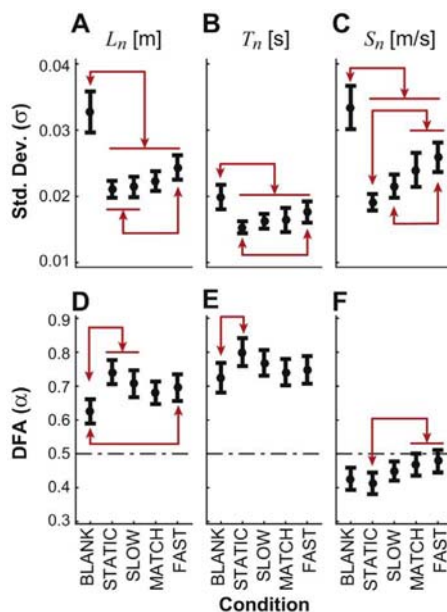
Two-factor (Subject  $\times$  Condition) repeated measures analyses of variance (ANOVA) tested for statistically significant differences of means, standard deviations, and DFA  $\alpha$  exponents of stride variables ( $T_n$ ,  $L_n$ ,  $S_n$ ), absolute treadmill position ( $P_n$ ), and deviations relative to the speed GEM ( $\delta_T$ ,  $\delta_P$ ) across the five experimental conditions. Tukey post-hoc analyses assessed differences between experimental conditions. Results were considered statistically significant if  $p < 0.05$ . All statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL).

### 3. Results

Mean values of  $L_n$  ( $F_{(4,76)} = 7.546$ ;  $p < 0.05$ ) and  $T_n$  ( $F_{(4,76)} = 7.306$ ;  $p < 0.05$ ) differed significantly across conditions. Post-hoc analyses indicated that participants adopted, on average, significantly shorter ( $p < 0.05$ ) and faster ( $p < 0.05$ ) strides in BLANK compared to the other four conditions (Fig. 2). By construction, mean values of  $S_n$  did not differ across conditions ( $F_{(4,76)} = 0.744$ ;  $p = 0.565$ , Fig. 2).

Standard deviations of  $L_n$  ( $F_{(4,76)} = 23.670$ ;  $p < 0.05$ ),  $T_n$  ( $F_{(4,76)} = 7.238$ ;  $p < 0.05$ ), and  $S_n$  ( $F_{(4,76)} = 23.613$ ;  $p < 0.05$ ) differed significantly across conditions. Participants exhibited significantly increased variability ( $\sigma$ ) for all three stride parameters ( $p < 0.05$ ) during BLANK compared to the other conditions (Fig. 3A–C). Significantly increased  $L_n$  variability was observed in FAST compared to STATIC and SLOW, whereas FAST elicited greater  $T_n$  variability compared to STATIC. Additionally, greater  $S_n$  variability was exhibited in MATCH and FAST compared to STATIC, and in FAST condition compared to SLOW (Fig. 3C).

For all experimental conditions, participants exhibited stride-to-stride statistical persistence (i.e.  $\alpha > 1/2$ ) in both  $L_n$  and  $T_n$  (Fig. 3D and E). Participants exhibited stride-to-stride statistical anti-persistence (i.e.  $\alpha < 1/2$ ) in  $S_n$  across all conditions (Fig. 3F). DFA  $\alpha$ 's of  $L_n$



**Fig. 3.** Variability ( $\sigma$ ) and Statistical Persistence ( $\alpha$ ) of Stride Parameters. (A–C) Variability (within-trial standard deviations:  $\sigma$ ) for stride lengths ( $L_n$ ), times ( $T_n$ ), and speeds ( $S_n$ ) during each of the five conditions (BLANK, STATIC, SLOW, MATCH, and FAST). (D and F) DFA scaling exponents ( $\alpha$ ) for  $L_n$ ,  $T_n$ , and  $S_n$  during all conditions. Error bars represent between-participant  $\pm 95\%$  confidence intervals. Red arrows/lines indicate statistically significant differences between individual conditions. During the BLANK condition, increased variability was observed for all three stride parameters (A–C) compared to all other experimental conditions (STATIC, SLOW, MATCH, and FAST). Across all conditions, participants exhibited stride-to-stride statistical persistence (i.e.  $\alpha > 0.5$ ) in both (D) stride lengths ( $L_n$ ) and (E) stride times ( $T_n$ ), suggesting that deviations were not immediately corrected on consecutive strides. (F) Conversely, participants exhibited stride-to-stride statistical anti-persistence (i.e.  $\alpha < 0.5$ ) for stride speeds ( $S_n$ ), suggesting these deviations were more tightly controlled. Additionally, participants exhibited significantly more statistical anti-persistence (i.e., more negative  $\alpha$ ) for  $S_n$  in STATIC compared to FAST and MATCH.

( $F_{(4,76)} = 5.323$ ;  $p < 0.05$ ),  $T_n$  ( $F_{(4,76)} = 2.020$ ;  $p < 0.05$ ), and  $S_n$  ( $F_{(4,76)} = 2.692$ ;  $p < 0.05$ ) differed significantly across conditions ( $p < 0.05$ ). In the BLANK condition, participants exhibited significantly less statistical persistence in  $L_n$  compared to the STATIC, SLOW and FAST conditions ( $p < 0.05$ , Fig. 3D); and significantly greater statistical persistence in  $T_n$  compared to STATIC ( $p < 0.05$ , Fig. 3E). For  $S_n$ , participants exhibited significantly greater statistical anti-persistence in FAST and MATCH compared to STATIC ( $p < 0.05$ , Fig. 3F).

Fig. 4 shows GEM plots and time series for 1 typical trial for each of 3 conditions. Distributions of [ $T_n$ ,  $L_n$ ] (Fig. 4A) demonstrated greater variance along and relatively less variance perpendicular to the speed GEM in all experimental conditions. Notably, in BLANK, this participant exhibited qualitatively more variance in *all* directions (Fig. 4A). In STATIC compared to MATCH, this participant exhibited more variance along and less variance perpendicular to the speed GEM compared to MATCH (Fig. 4A). Corresponding time series data of  $\delta_T$  fluctuations exhibited larger amplitudes than  $\delta_P$  fluctuations across all conditions (Fig. 4B). Fluctuations in  $P_n$  were also sustained across multiple strides, with the magnitudes of these fluctuations generally larger in BLANK compared to the other four conditions (Fig. 4C; only BLANK, STATIC and MATCH shown).

These qualitative observations (Fig. 4) were confirmed by our quantitative analyses (Fig. 5). Standard deviations of  $\delta_T$  ( $F_{(4,76)} = 7.848$ ;  $p < 0.05$ ),  $\delta_P$  ( $F_{(4,76)} = 7.557$ ;  $p < 0.05$ ), and  $P_n$  ( $F_{(4,76)} = 9.695$ ;  $p < 0.05$ ) differed significantly across conditions. Participants exhibited greater variability ( $\sigma$ ) for  $\delta_T$  than for  $\delta_P$  deviations across all conditions (Fig. 5A and B), as expected [6]. Participants also exhibited significantly greater ( $p < 0.05$ ) variability of  $\delta_T$  deviations

and significantly decreased variability of  $\delta_P$  deviations (Fig. 5A and B) in STATIC compared to the other four conditions ( $p < 0.05$ ; Fig. 5A and B). Variability ( $\sigma$ ) of  $P_n$  was lowest in STATIC compared to the other four conditions ( $p < 0.05$ , Fig. 5C).

Participants exhibited greater statistical persistence for  $\delta_T$  than for  $\delta_P$  fluctuations across all conditions (Fig. 5D and E). No significant differences were found in statistical persistence for  $\delta_T$  ( $F_{(4,76)} = 1.445$ ;  $p = 0.227$ , Fig. 5D). However, the statistical anti-persistence of  $\delta_P$  ( $F_{(4,76)} = 2.590$ ;  $p < 0.05$ , Fig. 5E) differed significantly across conditions. Participants exhibited significantly greater statistical anti-persistence in  $\delta_P$  for FAST and MATCH compared to STATIC ( $p < 0.05$ , Fig. 5E). Stride-to-stride fluctuations in  $P_n$  exhibited very strong statistical persistence that did not differ across conditions ( $F_{(4,76)} = 2.075$ ;  $p = 0.092$ , Fig. 5F).

For several of the reported measures, the Subject  $\times$  Condition interactions were also statistically significant ( $p < 0.05$ ). However, while the data showed that individual participants exhibited different changes in their responses across conditions, these differences were not systematic and do not detract from the overall trends due to the main effect of Condition.

#### 4. Discussion

Systematic manipulation of relative optic flow speed or removal of optic flow during treadmill walking significantly altered both how *quickly* parameter fluctuations were actively corrected (DFA scaling exponents,  $\alpha$ ) and how *successful* participants were at correcting these fluctuations (standard deviations,  $\sigma$ ).

Consistent with previous studies [6,8–10], across all conditions, participants *rapidly* corrected deviations in  $S_n$  (as indicated by  $\alpha < 0.5$ , Fig. 3F) to try and maintain approximately constant stride speed at each new stride. However, when walking with static visual information but *zero* optic flow (STATIC) compared to the non-zero optic flow conditions (MATCH and FAST), participants exhibited significantly greater active correction (smaller DFA  $\alpha$ ) of  $S_n$ . These results support our hypothesis that participants would more-rapidly correct stride speed deviations in a zero optic flow context compared to non-zero optic flow contexts. This suggests that small deviations in  $S_n$  induced corresponding changes in optic flow that were easier to detect (as indicated by greater active speed correction) when the nominal optic flow was zero (Fig. 3F), consistent with Weber's law. Moreover, although our analysis focused on how each stride affected subsequent strides and participants were not able to vary their average walking speed (as it was fixed), our results remain consistent with past work [11–15] that documented significant effects of optic flow modulations on average walking speed. Our results further identified changes in stride-to-stride stepping strategies, and specifically active error correction. These findings provide deeper insights into how the temporal characteristics of optic flow influence walking.

Further, participants exhibited significantly less  $S_n$  variability (Fig. 3C), and  $\delta_P$  variability (Fig. 5B), in STATIC compared to the non-zero optic flow conditions (MATCH and FAST). Thus, participants were more *successful* at implementing their strategy to maintain constant speed at each stride during the zero optic flow condition (STATIC), again consistent with Weber's law. Notably, participants also exhibited more variance tangent ( $\sigma(\delta_T)$ ) to the speed GEM in STATIC compared to all the non-zero optic flow conditions (SLOW, MATCH and FAST; Fig. 5A). This indicates that, on average, participants were better able to exploit the speed GEM during the *no* optic flow condition compared to the non-zero optic flow conditions.

Removing visual information (BLANK condition) led participants to appear to walk more cautiously: they took shorter and faster steps (Fig. 2). However, participants' level of stride-to-stride control during BLANK did not differ from the other four conditions for either  $S_n$  (Fig. 3F),  $\delta_T$ ,  $\delta_P$  (Fig. 5D and E), or  $P_n$  (Fig. 5F). Conversely, stride-to-stride fluctuations for  $L_n$  and  $T_n$  were significantly less persistent for



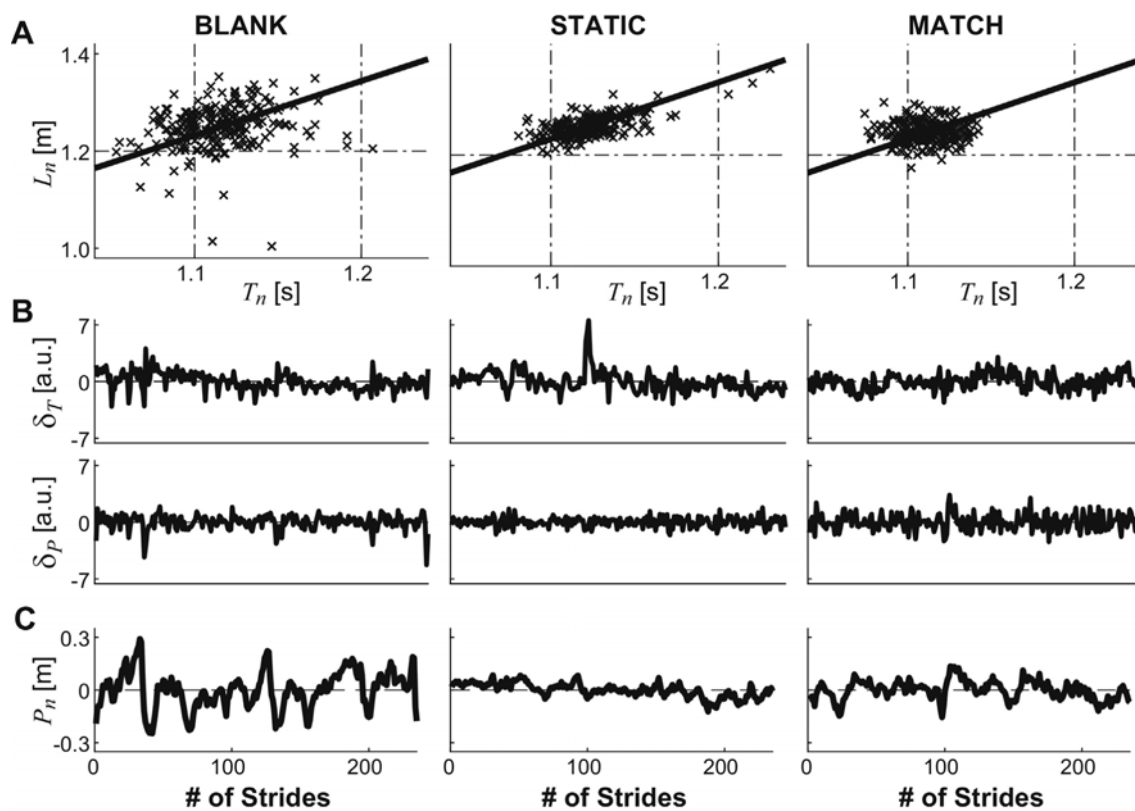


Fig. 4. Example GEM Plots and Time Series Data for a Typical Participant.

(A) Example  $[T_n, L_n]$  data from a typical participant for the BLANK, STATIC, and MATCH conditions. Each individual symbol ('x') represents an individual stride  $n$ . The solid diagonal line represents the speed GEM ( $v_w = 1.12$  m/s, see Fig. 1B). (B) Time series of  $\delta_T$  and  $\delta_P$  deviations for the data shown in (A). Qualitatively,  $\delta_T$  deviations exhibit larger amplitudes compared to  $\delta_P$  deviations across these experimental conditions. Additionally, the STATIC condition appears to have smaller and larger amplitudes of  $\delta_P$  and  $\delta_T$  deviations, respectively, compared to the MATCH condition. (C) Time series data of absolute treadmill position  $P_n$  for the data shown in (A-B). Qualitatively, this participant exhibited substantial deviations in absolute position that were sustained across multiple strides and suggests very strong statistical persistence. Additionally, the magnitude of this "drift" was larger in the BLANK condition compared to the STATIC and MATCH conditions.

BLANK compared to STATIC. Thus, while participants still generally employed the strategy to maintain stride speed ( $S_n$ , or equivalently  $\delta_P$ ), *how* they achieved this (i.e., by correcting  $L_n$  &  $T_n$  deviations relative to their mean values) was significantly altered, as indicated by increased active stride-to-stride correction (Fig. 3D and E). This made them, on average, less successful at maintaining constant speed over the long term (Fig. 3C). Further, participants also exhibited significantly greater variability for both stepping movements (Fig. 3A–C) and position on the treadmill (Fig. 5C) in BLANK compared to the optic flow conditions. Participants did wear goggles to block the lower visual field only in this BLANK condition. Visual information from the lower visual field can be important, particularly when walking over terrain that is irregular or unpredictable [28]. Here, however, participants walked on a continuous flat surface and were instructed to look straight ahead at a very large screen. Likewise, humans elicit all available visual information from their fields of view to control locomotion [29]. Thus, we anticipate that having participants wear these goggles likely had little effect and did not contribute to the substantial stepping differences observed in the BLANK condition compared to the other conditions.

Trying to maintain speed is only one of *many* possible strategies that can successfully achieve treadmill walking [6]. For example, one valid alternative might be to try to stay in the same position on the treadmill. Maintaining either constant-speed or constant-position leads to the same *average* speed and position. However, these stride-to-stride control strategies predict very different fluctuation *dynamics* (i.e., standard deviations ( $\sigma$ ) and DFA ( $\alpha$ ) exponents) for both speed ( $S_n$ ) and position ( $P_n$ ) [7]. In the present study, across all conditions, participants did not tightly regulate ( $\alpha > 1/2$ )  $P_n$  deviations. Instead, healthy participants exhibited deviations in  $P_n$  that were sustained across multiple strides

(Fig. 4C), indicating very weak regulation of position [7]. However,  $P_n$  variability was lowest in the STATIC condition, increased as optic flow speed increased, and was greatest in BLANK when all visual references were removed (Fig. 5C). While participants did not change how they *regulated* these fluctuations from stride to stride (Fig. 5F), the variability data demonstrate optic flow affected how effective they were at maintaining position. Although healthy adults choose to maintain constant stride speed at each stride and not constant position, decreased absolute treadmill position variability suggests participants were better able (on average, Fig. 5C) to detect small treadmill position changes during the STATIC condition compared to the other four conditions, again in a manner consistent with Weber's law. Both the speed and position effects indicate that the temporal characteristics of optic flow significantly influence the ability of healthy adults to detect and regulate these small stepping fluctuations.

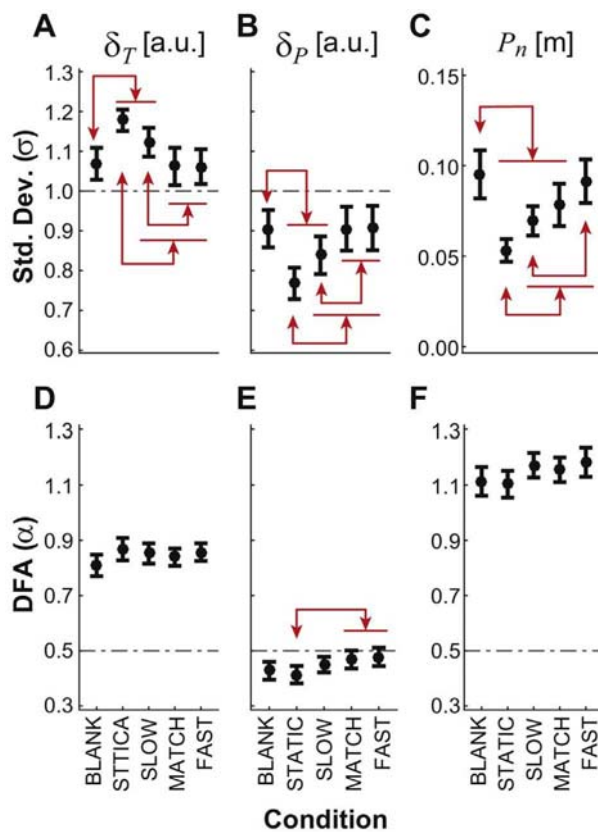
Optic flow influenced both how *quickly* humans corrected stride speed deviations and how *successful* they were at minimizing stride speed and treadmill position variability. These findings provide greater understanding of how experimental optic flow modulations may or may not influence stride-to-stride stepping strategies.

#### Conflict of interest statement

The authors declare that there are no conflicts of interest associated with this work.

#### Acknowledgement

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**Fig. 5.** Variability ( $\sigma$ ) and Statistical Persistence ( $\alpha$ ) of both  $\delta_T$  and  $\delta_P$  deviations and Absolute Treadmill Position ( $P_n$ ).

(A–C) Within-trial stride-to-stride variability (standard deviations:  $\sigma$ ) exhibited during each experimental condition (BLANK, STATIC, SLOW, MATCH, FAST). (D and F) DFA scaling exponents ( $\alpha$ ) exhibited during each condition. Error bars represent between-participant  $\pm$  95% confidence intervals. Red arrows/lines indicate statistically significant differences between conditions. Participants exhibited greater variability (A) along the GEM ( $\delta_T$ ) than (B) perpendicular to the GEM ( $\delta_P$ ) across all five experimental conditions. Further, a decrease in variability of  $\delta_P$  deviations and an increase in the variability of  $\delta_T$  deviations was observed in STATIC compared to the other four conditions (BLANK, SLOW, MATCH, and FAST). Participants exhibited greater statistical persistence for (D)  $\delta_T$  than for (E)  $\delta_P$  across all five conditions. Participants' absolute positions on the treadmill ( $P_n$ ) exhibited (C) greater variability in BLANK compared to STATIC, SLOW, and MATCH, and (D) very strong statistical persistence across all conditions; indicating these deviations in absolute position were not tightly controlled.

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## Research



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# How do prosthetic stiffness, height and running speed affect the biomechanics of athletes with bilateral transtibial amputations?

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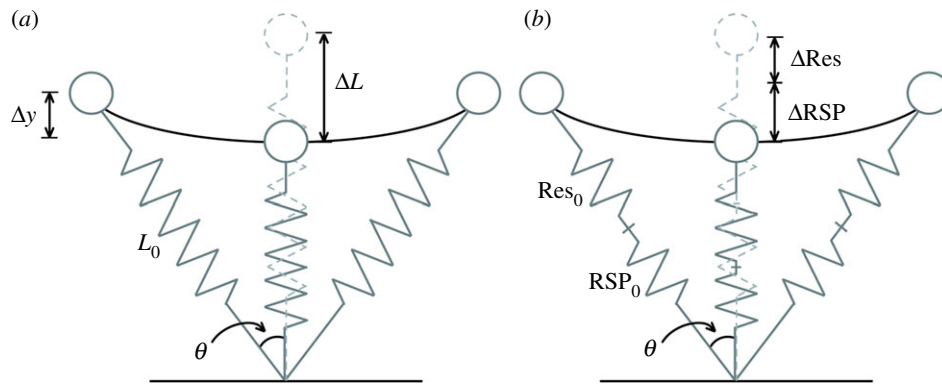
Limited available information describes how running-specific prostheses and running speed affect the biomechanics of athletes with bilateral transtibial amputations. Accordingly, we quantified the effects of prosthetic stiffness, height and speed on the biomechanics of five athletes with bilateral transtibial amputations during treadmill running. Each athlete performed a set of running trials with 15 different prosthetic model, stiffness and height combinations. Each set of trials began with the athlete running on a force-measuring treadmill at  $3 \text{ m s}^{-1}$ , subsequent trials incremented by  $1 \text{ m s}^{-1}$  until they achieved their fastest attainable speed. We collected ground reaction forces (GRFs) during each trial. Prosthetic stiffness, height and running speed each affected biomechanics. Specifically, with stiffer prostheses, athletes exhibited greater peak and stance average vertical GRFs ( $\beta = 0.03$ ;  $p < 0.001$ ), increased overall leg stiffness ( $\beta = 0.21$ ;  $p < 0.001$ ), decreased ground contact time ( $\beta = -0.07$ ;  $p < 0.001$ ) and increased step frequency ( $\beta = 0.042$ ;  $p < 0.001$ ). Prosthetic height inversely associated with step frequency ( $\beta = -0.021$ ;  $p < 0.001$ ). Running speed inversely associated with leg stiffness ( $\beta = -0.58$ ;  $p < 0.001$ ). Moreover, at faster running speeds, the effect of prosthetic stiffness and height on biomechanics was mitigated and unchanged, respectively. Thus, prosthetic stiffness, but not height, likely influences distance running performance more than sprinting performance for athletes with bilateral transtibial amputations.

## 1. Background

During running, the vertical position of an athlete's centre of mass (CoM) reaches its lowest position at mid-stance and its highest position at the middle of the aerial phase. This fundamental cyclic movement is due to the spring-like behaviour of the stance leg and is well described by a spring–mass model [1–6]. The model simplifies the leg's musculoskeletal system during running to a massless linear leg spring supporting a point mass that represents the athlete's CoM [1–6] (figure 1). During the first half of ground contact, elastic potential energy is stored in the compressed leg spring. Subsequently, the stored mechanical energy is released during the second half of ground contact as the leg spring recoils, thereby accelerating the CoM forward and upward into the aerial phase [7]. The magnitude of the stored and returned mechanical energy is inversely related to leg stiffness, and is thought to influence running performance by altering the generation of muscular mechanical work [7–9], and contraction velocities [10].

Fundamentally, the spring–mass model characterizes running biomechanics for athletes with [6,11–13] and without lower-limb amputations [1–6]; however, the product of step length and step frequency ultimately dictates running speed. Step length can be determined from the product of the horizontal distance travelled by the CoM during ground contact (contact length) and the stance





**Figure 1.** Illustration of a (a) spring–mass model and (b) spring–mass model with two in-series leg springs. Body mass is represented as a point mass (circle) and the touch-down angle is indicated by  $\theta$ . (a) The stance leg is represented by a massless linear spring for non-amputees, and (b) two in-series massless linear springs for athletes with bilateral amputations. The initial leg length ( $L_0$ ) shortens ( $\Delta L$ ), and vertical height ( $\Delta y$ ) decreases during the stance phase of running. Modelled residual limb length ( $Res_0$ ) and prosthetic height ( $RSP_0$ ) compress and extend ( $\Delta Res$  and  $\Delta RSP$ ) during the stance phase of running.

average vertical ground reaction force (GRF) magnitude normalized to body weight [14,15]. Step frequency can be calculated from the reciprocal of the sum of ground contact time and the subsequent aerial time [14,15]. Thus, the spring–mass model describes running biomechanics, while kinematic and kinetic parameters dictate running speed.

There is limited available information regarding how athletes with bilateral transtibial amputations, who run with passive-elastic running-specific prostheses (RSPs), adapt their biomechanics to achieve different running speeds. That is because to date merely three studies have reported biomechanics from a total of two athletes with bilateral transtibial amputations across running speeds [6,16,17], and because the running biomechanics of athletes with unilateral transtibial amputations (affected and unaffected leg) and non-amputees differ from those of athletes with bilateral transtibial amputations [6,16–18]. Collectively, as constant running speed is increased from 2.5 to 8.0 m s<sup>-1</sup>, athletes with bilateral transtibial amputations decrease leg stiffness, increase contact length [6], increase stance average vertical GRF [16], decrease contact time and maintain a nearly constant aerial time [16]. Beyond 8 m s<sup>-1</sup>, the same biomechanical trends persist except that stance average vertical GRFs plateau and aerial times decrease [16]. Therefore, athletes with bilateral transtibial amputations increase both step length and step frequency to achieve running speeds from 2.5 to 8.0 m s<sup>-1</sup>, while they primarily increase step frequency to achieve speeds faster than 8.0 m s<sup>-1</sup>. However, these trends are based on data from two athletes, thus a greater sample size is needed to confirm or refute these results.

Further, it is uncertain if the biomechanical changes with altered running speeds are inherent to athletes with bilateral transtibial amputations or if they are due to the characteristics of their RSPs. For example, many researchers and governing institutions speculate that prosthetic stiffness and height have a strong influence on the biomechanics and running performance of athletes with bilateral transtibial amputations [6,11,19,20]. In our previous study [11], we found that the use of stiffer RSPs by athletes with bilateral transtibial amputations was correlated with increased overall leg stiffness, increased residual limb stiffness, faster step frequencies and increased metabolic cost at relatively slow running speeds (2.5 and 3.0 m s<sup>-1</sup>). Yet, it remains uncertain whether running speed alters the influence of prosthetic stiffness on biomechanics. Because prosthetic stiffness slightly increases with greater

applied force [21], and residual limb stiffness is positively associated with prosthetic stiffness [11], the leg stiffness and step frequency of athletes with bilateral transtibial amputations should theoretically increase with running speed. Yet, the leg stiffness of such athletes has been reported to decrease with faster running speeds [6], indicating that the influence of prosthetic stiffness may be mitigated at faster running speeds.

Athletes with bilateral transtibial amputations participate in events that span a broad range of running speeds; therefore, it is important to understand how prosthetic stiffness, height and speed affect biomechanics. Accordingly, the purpose of this study was to quantify how changes in prosthetic stiffness, height and running speed affect the biomechanics of athletes with bilateral transtibial amputations. Based on our previous study [11], we hypothesized that across running speeds, (i) the use of stiffer RSPs would increase leg stiffness and step frequency and (ii) the use of taller RSPs would be independent of the biomechanical variables that govern leg stiffness and running speed. We also hypothesized that (iii) faster running speeds would lessen the influence of prosthetic stiffness on biomechanical parameters.

## 2. Participants and methods

### 2.1. Participants

Five male athletes with bilateral transtibial amputations participated (table 1). Four athletes primarily compete in sprinting (less than or equal to 400 m) and/or jumping track and field events and one athlete primarily competes in distance running events (greater than or equal to 5000 m) (table 1). Each athlete had over 1 year of experience running with passive-elastic RSPs, and gave informed written consent according to the protocol that was approved by the Colorado Multiple Institutional Review Board and the USAMRMC Office of Research Protection, Human Research Protection Office.

### 2.2. Protocol

Initially, each participant completed a fitting and accommodation session. During this session, we collected anthropometric measurements to determine the tallest prosthetic height that each participant could use to compete in track and field races according to the International Paralympic Committee (IPC) guidelines [19]. Next, a certified prosthetist aligned each participant with three commonly used prosthetic models (Freedom Innovations Catapult FX6, Irvine, CA, USA; Össur Cheetah Xtend, Reykjavik, Iceland;

**Table 1.** Participant characteristics: age, mass, cause of amputations and primary event(s). The maximum standing height and corresponding leg lengths allowed in track and field races sanctioned by the International Paralympic Committee (IPC) [19]. The resulting Catapult, Cheetah Xtend and 1E90 Sprinter prosthesis leg lengths represent the closest attainable maximum IPC-regulated leg lengths from each participant and prosthetic model combination [19]. Leg lengths were measured from the greater trochanters to the most distal locations of the unloaded prostheses.

participants	age (years)	mass (kg)	cause of amputations	primary event(s)	max IPC height (m)	max IPC leg length (m)	Catapult leg length (m)	Cheetah Xtend leg length (m)	1E90 Sprinter leg length (m)
1	25	69.3	congenital	100 m/ 200 m	1.80	0.97	1.12	0.97	0.97
2	23	76.3	congenital	long jump	1.88	1.07	1.07	1.07	1.04
3	18	75.0	congenital	100 m/ 200 m	1.87	1.05	1.05	1.05	1.05
4	31	70.4	trauma	400 m	1.90	1.10	1.10	1.10	1.10
5	27	70.5	infection	5000 m	1.87	1.06	1.06	1.06	1.06
average	24.8	72.3			1.86	1.05	1.08	1.05	1.04
s.d.	4.8	3.1			0.04	0.05	0.03	0.05	0.04

Ottobock 1E90 Sprinter, Duderstadt, Germany) at the manufacturer's recommended and  $\pm 1$  stiffness categories at the prosthetic height that produced the IPC maximum competition height and  $\pm 2$  cm. We chose these stiffness and height configurations because they have been reported to elicit biomechanical changes during running in athletes with transtibial amputations [11,22,23] and they enabled us to recruit athletes spanning a wide range of body masses and heights.

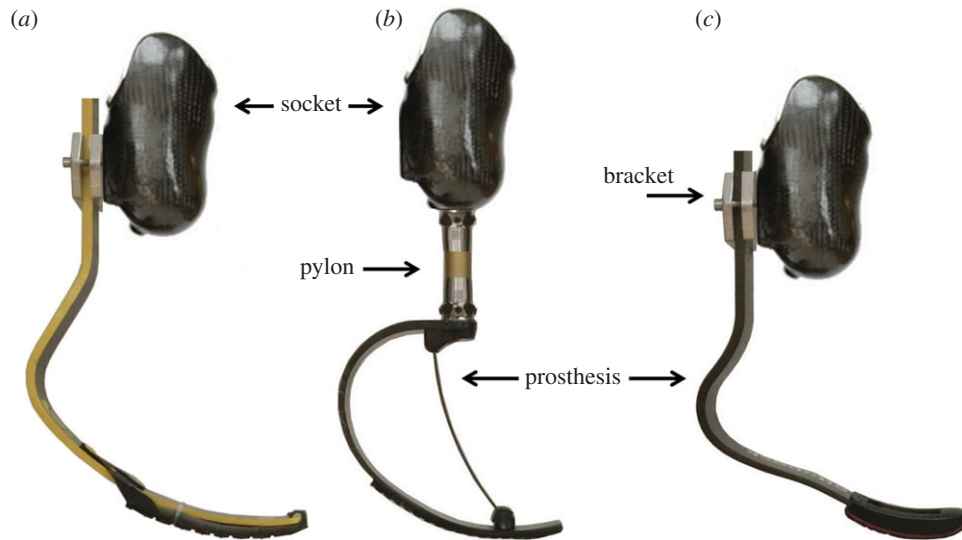
Each RSP functions as a spring through the storage and return of mechanical energy during stance. The Catapult prostheses are 'C' shaped and attach distally to sockets via connecting aluminium pylons. Each carbon-fibre or fibreglass socket (check socket) surrounds a residual limb and is secured with suction or a locking mechanism (figure 2). The Cheetah Xtend and 1E90 Sprinter prostheses are 'J'-shaped and mount to the posterior wall of the socket. After establishing the heights of the J-shaped RSPs, the prostheses are typically bolted directly to the sockets. To preserve the J-shaped RSPs, secure them to the sockets, and alter prosthetic height between trials, we constructed custom aluminium brackets that were bolted to the sockets (figure 2).

Owing to participant residual limb lengths and available prosthetic components, we were unable to match the maximum IPC competition height for some participants with certain prosthetic models. For these cases, we set prosthetic height as close as possible to the maximum IPC competition height. If the closest attainable height was taller than the maximum IPC competition height, we set that height as the baseline height for the respective participant and RSP combination and ensuing prosthetic height alterations were +2 and +4 cm. If the closest achievable height was shorter than the maximum IPC competition height, we set that height as the baseline height for the respective participant and RSP combination and subsequent prosthetic height alterations were -2 and -4 cm (table 1).

After participants were aligned to a prosthetic configuration, they ran on a motorized treadmill (Treadmetrix, Park City, UT, USA) at self-selected speeds until both the prosthetist and participant were satisfied with the comfort and function of the respective RSPs. Generally, athletes accommodated to each prosthetic model at the recommended stiffness category and height. When using C-shaped RSPs, athletes also ran at additional heights (i.e.  $\pm 2$  cm) to determine proper alignment with the taller/shorter pylons. When using J-shaped RSPs, the components and alignment were the same at each height per model, hence athletes did not typically accommodate to the additional heights. Four athletes used their personal competition sockets for the trials with the J-shaped RSPs, and they used their everyday/walking sockets when equipped with the C-shaped RSPs. For the other athlete, a prosthetist fabricated custom sockets that replicated the participant's competition sockets (suspension, internal dimensions, etc.) for use with the C- and J-shaped RSPs.

On subsequent days, participants performed a session of one to three sets of treadmill running trials [6]. Each set of treadmill running trials started with the participant running at  $3 \text{ m s}^{-1}$  and following successful trials, treadmill speed was incremented  $1 \text{ m s}^{-1}$  for the next trial. A successful trial was determined if the participant was able to maintain forward position on the treadmill while taking 20 consecutive steps [6,14,16,24]. If the participant was unable to maintain forward position on the treadmill for 20 consecutive steps, the trial was deemed unsuccessful. Ad libitum rest followed each trial. Following unsuccessful trials and rest periods, participants were given the option to retry the preceding trial's speed, or deem the last successful trial as their top speed with the given prosthetic configuration.

Participants were given two options to commence each treadmill running trial. The first option began with the participant straddling the treadmill belt while it sped up to the desired speed. Once the treadmill was up to speed, the participant lowered himself onto the moving treadmill belt using the handrails.



**Figure 2.** From left to right, (a) the Össur Cheetah Xtend prosthesis (J-shaped) at a representative recommended height, (b) the Freedom Catapult FX6 prosthesis (C-shaped) at a representative height of +2 cm and (c) the Ottobock 1E90 Sprinter prosthesis (J-shaped) at a representative height of −2 cm. The C-shaped prostheses are connected to sockets via aluminium pylons, and the J-shaped prostheses are connected to sockets via custom aluminium brackets. (Online version in colour.)

The participant then took a few steps on the belt and, when comfortable, began to run without handrail assistance, initiating the step count. The second option allowed each participant to begin by standing on the static treadmill belt. The participant then accelerated with the treadmill belt until the target speed was achieved. Once the treadmill achieved the desired speed, we began to count steps as the participant continued to run on the treadmill. For each trial, participants were allowed to choose either starting technique.

Each participant ran using 15 different combinations of prosthetic model, stiffness category and height. At first, participants ran using each model at three different stiffness categories (recommended and  $\pm 1$ ) at the IPC maximum competition height. The stiffness category for each prosthetic model that elicited the fastest top speed was considered optimal. Subsequently, participants ran using the optimal stiffness category of each prosthetic model at two additional heights ( $\pm 2$  cm). We randomized the trial order beginning with the nine prosthetic model and stiffness category combinations at the maximum IPC competition height. Once a participant completed trials at all three stiffness categories with a certain prosthetic model, we randomly inserted the altered height trials for a respective model at the optimal stiffness category into the trial order.

### 2.3. Prosthetic stiffness

Prosthetic stiffness categories are recommended to athletes by the respective manufacturers based on user body mass, with larger athletes being recommended numerically greater stiffness categories [25–27]; numerically greater stiffness categories indicate mechanically stiffer ( $\text{kN m}^{-1}$ ) prostheses [21]. As recommended stiffness ( $\text{kN m}^{-1}$ ) differs between prosthetic models [21], we calculated prosthetic stiffness using the peak vertical GRFs measured from each leg during each trial (present study) and the force–displacement equations from Beck *et al.* [21]. Next, we divided the measured peak GRF magnitude by the estimated prosthetic displacement to yield stiffness. Prosthetic stiffness values were previously only recorded from participants with transtibial amputations running at 3 and 6  $\text{m s}^{-1}$  [21]. Thus, we calculated prosthetic stiffness for trials at 3 and 6  $\text{m s}^{-1}$  and then derived prosthetic stiffness at 4, 5 and 7  $\text{m s}^{-1}$  assuming a linear relationship between prosthetic stiffness and running speed. We did not estimate prosthetic stiffness beyond 7  $\text{m s}^{-1}$ .

### 2.4. Data collection and stride count

We measured GRFs throughout the duration of each running trial. We collected GRFs at 1000 Hz, filtered them using a fourth-order low-pass Butterworth filter with a 30 Hz cut-off [11,22,28,29], and then used the filtered data to calculate the mean GRF parameters, stride kinematics and leg stiffness values with a custom Matlab script (Mathworks Inc., Natick, MA, USA). We set the vertical GRF threshold at 20 N to detect periods of ground contact. For each trial, participants ran with a reflective marker on the distal end of one of their RSPs, and we tracked its position at 200 Hz (Vicon Nexus, Oxford, UK). We filtered the position data using a fourth-order low-pass Butterworth filter with a 7 Hz cut-off [30,31] to determine the running speed during ground contact of the respective RSP using a custom Matlab script.

### 2.5. Data analysis

We calculated overall leg stiffness ( $k_{\text{leg}}$ ) as the quotient of peak vertical GRF ( $F_{\text{peak}}$ ) and peak leg spring compression ( $\Delta L$ ) during ground contact (figure 1):

$$k_{\text{leg}} = \frac{F_{\text{peak}}}{\Delta L}. \quad (2.1)$$

Peak leg spring compression ( $\Delta L$ ) was calculated using initial leg length ( $L_0$ ), the distance from the greater trochanter to the distal end of the unloaded RSP [6,11,24], theta ( $\theta$ ), the angle of the leg spring at initial ground contact relative to vertical (figure 1), running speed ( $v$ ) and ground contact time ( $t_c$ ):

$$\theta = \sin^{-1} \left( \frac{v t_c}{2 L_0} \right). \quad (2.2)$$

Next, peak leg spring compression ( $\Delta L$ ) was determined using peak vertical displacement of the CoM during ground contact ( $\Delta y$ ), calculated by twice integrating the vertical acceleration of the CoM with respect to time [32]:

$$\Delta L = \Delta y + L_0(1 - \cos \theta). \quad (2.3)$$

Moreover, because biological legs and RSPs have relatively linear force–displacement profiles [2,21], we modelled participant leg stiffness ( $k_{\text{leg}}$ ) as two in-series linear springs (figure 1). We incorporated established measurements of prosthetic stiffness

**Table 2.** Average ( $\pm$  s.d.) recommended (Rec) prosthetic stiffness values ( $\text{kN m}^{-1}$ ) for a 70 kg athlete across running speeds and prosthetic stiffness values ( $\text{kN m}^{-1}$ ) from  $\pm 1$  stiffness categories across speeds. We averaged prosthetic stiffness values at each category for each model, and then averaged stiffness values across models for the respective recommended category (i.e. Rec, or  $\pm 1$ ). Prosthetic stiffness was related to running speed ( $p < 0.001$ ).

stiffness category	running speed ( $\text{m s}^{-1}$ )				
	3	4	5	6	7
−1	$22.6 \pm 1.7$	$23.4 \pm 2.2$	$24.3 \pm 3.1$	$25.2 \pm 4.2$	$26.0 \pm 5.3$
Rec	$25.3 \pm 1.6$	$26.0 \pm 2.1$	$26.8 \pm 3.0$	$27.4 \pm 3.8$	$28.4 \pm 5.0$
+1	$27.5 \pm 2.1$	$28.4 \pm 2.5$	$29.4 \pm 3.2$	$30.3 \pm 4.1$	$31.5 \pm 5.4$

( $k_{\text{RSP}}$ ) [21], and current measurements of leg stiffness to determine residual limb stiffness ( $k_{\text{res}}$ ) using the following equation:

$$\frac{1}{k_{\text{leg}}} = \frac{1}{k_{\text{res}}} + \frac{1}{k_{\text{RSP}}} \quad (2.4)$$

As aforementioned, running speed ( $v$ ) is the product of step length ( $L_{\text{step}}$ ) and step frequency ( $F_{\text{step}}$ ):

$$v = L_{\text{step}} \cdot F_{\text{step}} \quad (2.5)$$

Steps lengthen by increasing the horizontal distance travelled by the runner's CoM during stance (contact length) ( $L_c$ ), and by producing greater stance average vertical GRFs ( $F_{\text{avg}}$ ) relative to bodyweight (BW) [14,15]. Therefore, step length can be calculated using the following equation:

$$L_{\text{step}} = L_c \cdot \frac{F_{\text{avg}}}{\text{BW}} \quad (2.6)$$

We used the above equation because it enables us to further investigate the biomechanical variables that govern step length (i.e.  $L_c$  and  $F_{\text{avg}}/\text{BW}$ ) and therefore running speed. Step frequency is calculated from the reciprocal of the sum of ground contact time ( $t_c$ ) and subsequent aerial time ( $t_a$ ) [14,15]:

$$F_{\text{step}} = \frac{1}{t_c + t_a} \quad (2.7)$$

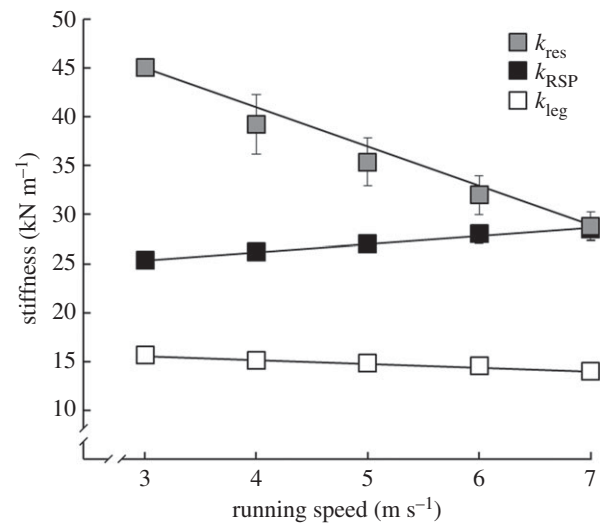
Thus, by combining equations (2.5), (2.6) and (2.7), running speed ( $v$ ) is calculated using the following equation:

$$v = L_c \cdot \frac{F_{\text{avg}}}{\text{BW}} \cdot \frac{1}{t_c + t_a} \quad (2.8)$$

For the complete derivation of the above equation, refer to [14,15].

## 2.6. Statistical analyses

We used a linear mixed model to evaluate the influence of prosthetic stiffness ( $\text{kN m}^{-1}$ ), height and running speed ( $3\text{--}9 \text{ m s}^{-1}$ ) on the biomechanical variables that comprise the spring–mass model and running speed (variables from equations (2.1) through (2.8)). We report the fixed effect ( $\beta$ ) from each statistically significant association (dependent variable =  $\beta$  independent variable + constant). We tested for all potential stiffness/speed and height/speed interactions. Additionally, prosthetic stiffness depends on the magnitude and orientation of the applied force [21], thus we performed a one-way ANOVA to determine whether running speed statistically influenced prosthetic stiffness. We set the level of significance at  $p = 0.05$  and performed statistical analyses using R-studio (Boston, MA, USA).



**Figure 3.** The average ( $\pm$  s.e.) stiffness of the overall leg ( $k_{\text{leg}}$ ), the prosthesis (RSP;  $k_{\text{RSP}}$ ) and the residual limb ( $k_{\text{res}}$ ) across 3 through  $7 \text{ m s}^{-1}$  and across all prosthetic configurations. Across all conditions, simple linear regression equations follow as:  $k_{\text{leg}} = -0.30 \text{ Speed} + 16.4$ ,  $R^2 = 0.05$ ,  $p < 0.001$ ;  $k_{\text{res}} = -4.0 \text{ Speed} + 56.0$ ,  $R^2 = 0.16$ ,  $p < 0.001$ ;  $k_{\text{RSP}} (\text{kN m}^{-1}) = 0.82 \text{ Speed} + 22.9$ ,  $R^2 = 0.07$ ,  $p < 0.001$ . Error bars indicate inter-subject variability and may be hidden behind the symbols.

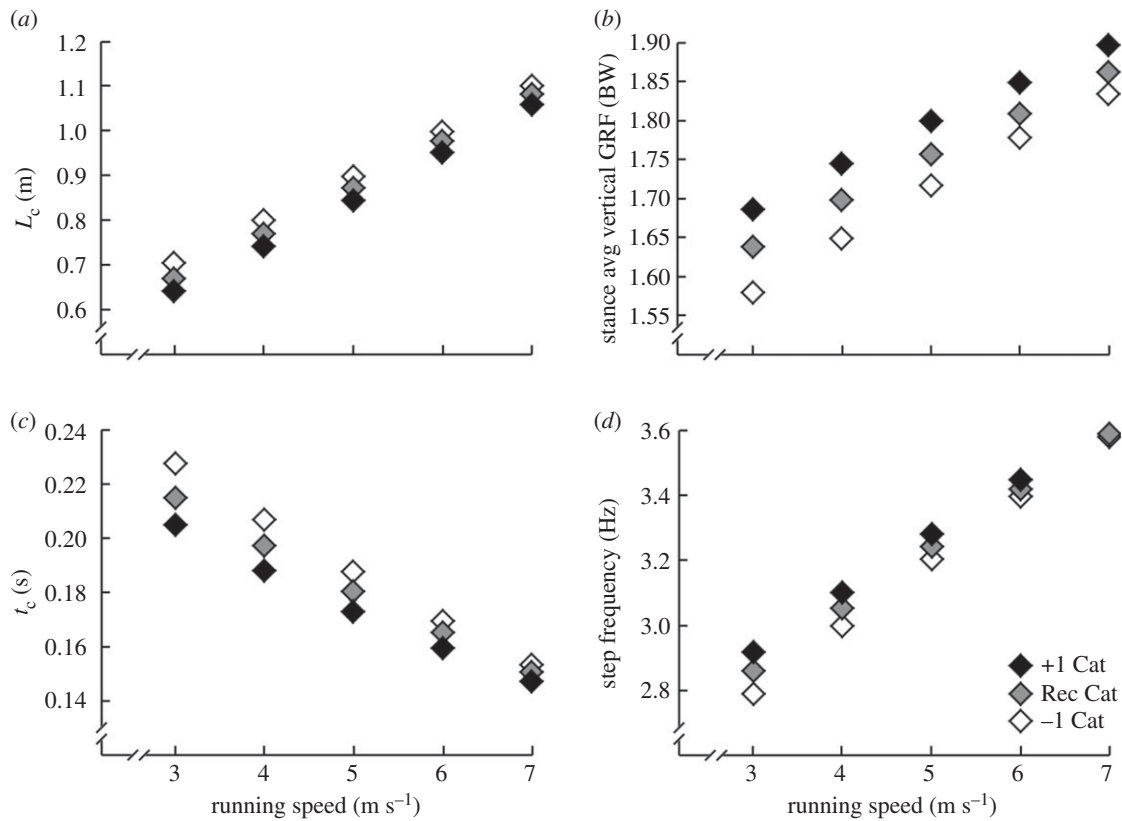
## 3. Results

Owing to the difficulties of determining running speed during the acceleration phase, some trials contained fewer than 20 steps at the desired speed. Consequently, we used the motion capture data to determine instantaneous running speed and only analysed steps that were taken at the desired speed. We excluded data from the last two steps of each trial to remove any potential biomechanical alterations that occurred while participants prepared to dismount the treadmill. We also excluded data from trials that had fewer than four consecutive steps at the desired speed. Additionally, due to saturation in the force signal, we removed 16 trials from the analysis. Nonetheless, we analysed 73 trials at speeds of 3, 5 and  $6 \text{ m s}^{-1}$ , 74 trials at  $4 \text{ m s}^{-1}$ , 72 trials at  $7 \text{ m s}^{-1}$ , 65 trials at  $8 \text{ m s}^{-1}$  and 37 trials at  $9 \text{ m s}^{-1}$ .

### 3.1. Prosthetic stiffness

Prosthetic stiffness increased with faster running speeds ( $p < 0.001$ ) (table 2). From 3 to  $7 \text{ m s}^{-1}$ , overall prosthetic stiffness averaged ( $\pm$  s.d.)  $25.4 \pm 3.0$ ,  $26.1 \pm 3.4$ ,  $27.1 \pm 4.0$ ,  $28.0 \pm 4.8$  and  $28.6 \pm 5.6 \text{ kN m}^{-1}$  at each successive speed (figure 3). Unless otherwise specified, all results were interpreted while





**Figure 4.** (a) Contact length ( $L_c$ ), (b) stance average vertical GRF, (c) contact time ( $t_c$ ) and (d) step frequency, while using RSPs averaged from three different models at one stiffness category below recommended ( $-1$  Cat), at recommended (Rec Cat) and at one stiffness category greater than recommended ( $+1$  Cat) across running speeds. Prosthetic stiffness categories correspond to a 70 kg athlete. See table 2 for prosthetic stiffness values ( $k_{RSP}$  in  $\text{kN m}^{-1}$ ) used at each speed ( $v$ ) and stiffness category recommendation. Biomechanical data are derived from statistical linear mixed models. The linear mixed model regression equations follow as: (a)  $L_c = 0.08 v - 0.02 k_{RSP} + 0.001 v \cdot k_{RSP} + 0.76$ ; (b) avg vertical GRF  $= 0.11 v + 0.03 k_{RSP} - 0.003 v \cdot k_{RSP} + 0.75$ ; (c)  $t_c = -0.038 v - 0.007 k_{RSP} + 0.001 v \cdot k_{RSP} + 0.446$ ; (d) step frequency  $= 0.315 v + 0.042 k_{RSP} - 0.005 v \cdot k_{RSP} + 1.258$ .

controlling for covariates (e.g. interpreting the effect of prosthetic stiffness on biomechanics while controlling for prosthetic height, running speed and interactions between prosthetic height and running speed). For every  $1 \text{ kN m}^{-1}$  increase in prosthetic stiffness, overall leg stiffness increased  $0.21 \text{ kN m}^{-1}$  ( $p < 0.001$ ), residual limb stiffness decreased  $2.09 \text{ kN m}^{-1}$  ( $p < 0.001$ ) (figure 3), contact length decreased  $1.7 \text{ cm}$  ( $p < 0.001$ ) and step frequency increased  $0.042 \text{ Hz}$  ( $p < 0.001$ ) (figure 4). Regarding the other spring-mass model variables, for every  $1 \text{ kN m}^{-1}$  increase in prosthetic stiffness,  $\theta$  increased  $0.004 \text{ rad}$  ( $p = 0.012$ ),  $\Delta y$  decreased  $0.19 \text{ cm}$  ( $p < 0.001$ ) (figure 5), peak vertical GRF increased  $0.03$  times BW ( $p < 0.001$ ) and  $\Delta L$  decreased  $0.07 \text{ cm}$  ( $p < 0.001$ ). Concerning the rest of the biomechanics that govern running speed, for every  $1 \text{ kN m}^{-1}$  increase in prosthetic stiffness, stance average vertical GRF increased  $0.03$  times BW ( $p < 0.001$ ) and contact time decreased  $0.007 \text{ s}$  ( $p < 0.001$ ) (figure 5).

## 3.2. Prosthetic height

Increasing prosthetic height by  $2 \text{ cm}$  resulted in no significant changes in overall leg stiffness ( $p = 0.756$ ) or residual limb stiffness ( $p = 0.668$ ), but did correlate with a  $2.3 \text{ cm}$  increased contact length ( $p < 0.001$ ) and  $0.021 \text{ Hz}$  decreased step frequency ( $p = 0.009$ ). For every  $2 \text{ cm}$  increase in prosthetic height,  $\theta$  decreased  $0.012 \text{ rad}$  ( $p < 0.001$ ),  $\Delta y$  increased  $0.16 \text{ cm}$  ( $p < 0.001$ ) and peak vertical GRF decreased by  $0.02$  times BW ( $p = 0.047$ ). Furthermore, for every  $2 \text{ cm}$  increase in prosthetic height, stance average vertical GRF

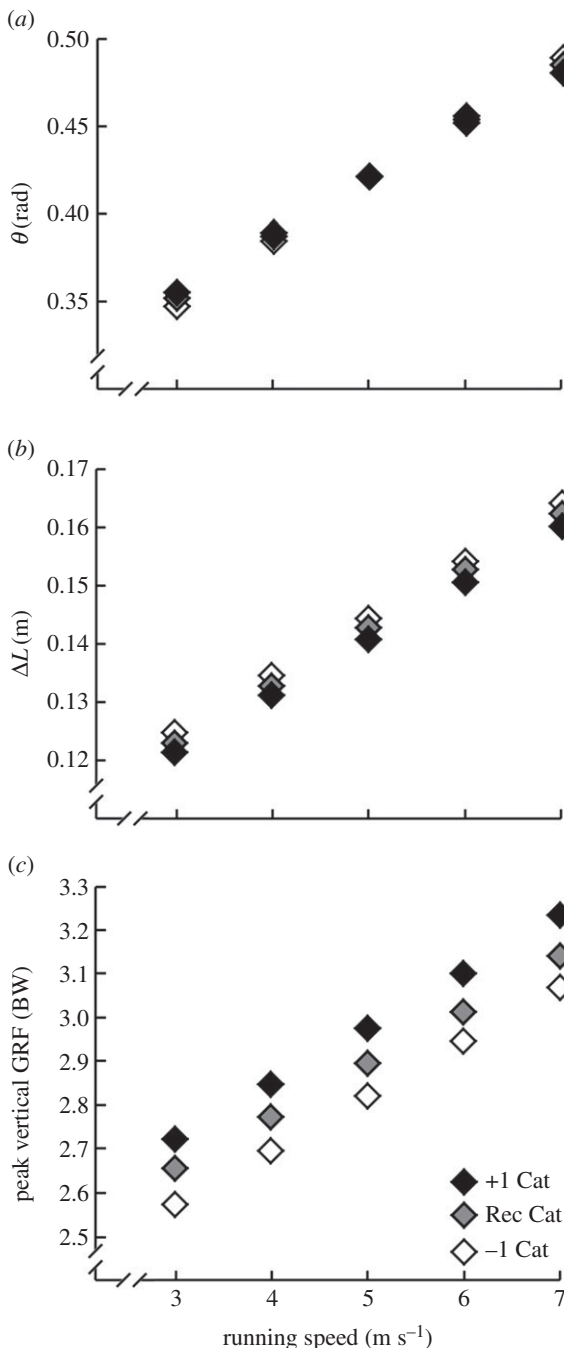
decreased  $0.25$  times BW ( $p < 0.001$ ) and contact time increased  $0.003 \text{ s}$  ( $p < 0.001$ ). Prosthetic height did not influence  $\Delta L$  ( $p = 0.130$ ).

## 3.3. Running speed

Each participant was able to achieve a running speed of  $9 \text{ m s}^{-1}$  with at least one prosthetic configuration. For every  $1 \text{ m s}^{-1}$  increase in running speed, overall leg stiffness decreased  $0.58 \text{ kN m}^{-1}$  ( $p < 0.001$ ), residual limb stiffness decreased  $9.42 \text{ kN m}^{-1}$  ( $p < 0.001$ ) (figure 3), contact length increased  $7.8 \text{ cm}$  ( $p < 0.001$ ) and step frequency increased  $0.32 \text{ Hz}$  ( $p < 0.001$ ) (figures 4 and 7). For every  $1 \text{ m s}^{-1}$  increase in running speed,  $\theta$  increased  $0.055 \text{ rad}$  ( $p < 0.001$ ),  $\Delta y$  decreased  $1.15 \text{ cm}$  ( $p < 0.001$ ), peak vertical GRF increased  $0.01$  times BW ( $p < 0.001$ ) and  $\Delta L$  increased  $1.00 \text{ cm}$  ( $p < 0.001$ ) (figure 5). Moreover, for every  $1 \text{ m s}^{-1}$  increase in running speed, stance average vertical GRF increased  $0.12$  times BW ( $p < 0.001$ ), and contact time decreased  $0.038 \text{ s}$  ( $p < 0.001$ ) (figure 4). Independently, running speed did not change peak vertical GRF magnitude ( $p = 0.743$ ).

## 3.4. Prosthetic stiffness/height and speed interaction effects

At faster running speeds, the influence of prosthetic stiffness on residual limb stiffness ( $\beta = 0.23$ ;  $p = 0.020$ ), contact length ( $\beta = 0.13$ ;  $p = 0.019$ ) and step frequency ( $\beta = -0.005$ ;  $p = 0.004$ ) (figure 5) was all diminished. Furthermore, for every  $1 \text{ m s}^{-1}$



**Figure 5.** (a) Touch-down angle ( $\theta$ ), (b) leg spring compression ( $\Delta L$ ) and (c) peak vertical GRF averaged from three different running-specific prosthetic models at one stiffness category below recommended ( $-1$  Cat), at recommended (Rec Cat) and at one stiffness category greater than recommended ( $+1$  Cat) across running speeds. Prosthetic stiffness categories correspond to a 70 kg athlete. See table 2 for prosthetic stiffness values ( $k_{RSP}$  in  $\text{kN m}^{-1}$ ) used at each speed ( $v$ ) and stiffness category recommendation. Biomechanical data are derived from statistical linear mixed models. The regression equations follow as: (a)  $\theta = 0.055 v + 0.004 k_{RSP} - 0.001$  Speed  $\cdot k_{RSP} + 0.145$ ; (b)  $\Delta L = 0.010 v - 0.001 k_{RSP} + 0.109$ ; (c) peak vertical GRF =  $0.10 v + 0.03 k_{RSP} + 1.59$ .

increase in running speed, the effect of increasing prosthetic stiffness  $1 \text{ kN m}^{-1}$  was associated with a  $0.001 \text{ rad}$  decreased  $\theta$  ( $p = 0.001$ ) (figure 4), and  $0.03 \text{ cm}$  increased  $\Delta y$  ( $p < 0.001$ ). For every  $1 \text{ m s}^{-1}$  increase in running speed, every  $1 \text{ kN m}^{-1}$  increase in prosthetic stiffness was related with a  $0.003$  times body weight decreased stance average vertical GRF ( $p < 0.001$ ), and a  $0.001 \text{ s}$  increase in contact time ( $p < 0.001$ )

(figure 5). No other prosthetic stiffness/height and speed interactions achieved statistical significance ( $p > 0.05$ ).

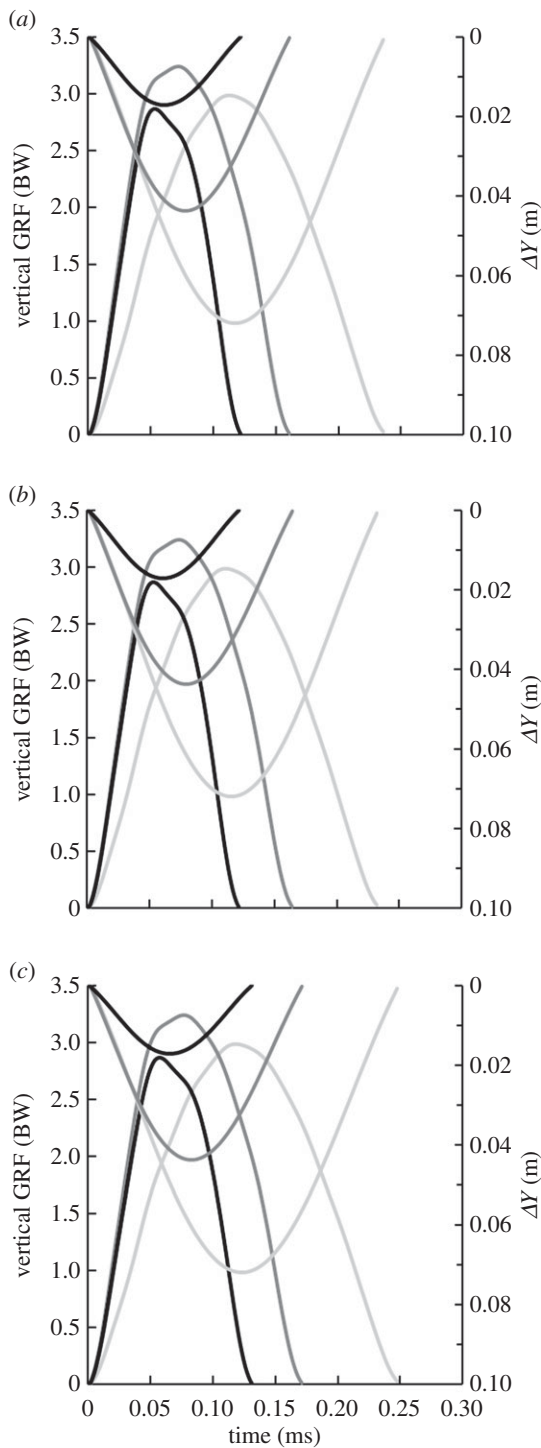
## 4. Discussion

The purpose of this study was to quantify how altered prosthetic stiffness, height and running speed affect the biomechanics of athletes with bilateral transtibial amputations. We accepted our initial hypothesis that the use of stiffer RSPs would result in increased overall leg stiffness and step frequency (figures 3 and 4). This extends the previous research, which concluded that at a single, slow running speed, athletes with bilateral transtibial amputations increase overall leg stiffness and step frequency with the use of stiffer RSPs [11]. However, the previous study's athletes demonstrated an extremely weak positive correlation between prosthetic stiffness and residual limb stiffness [11], contrasting this study's finding of an inverse relationship between prosthetic stiffness and residual limb stiffness (figure 3). This study's finding corresponds with the established observation that non-amputees inversely alter overall leg stiffness with changed in-series surface stiffness to maintain nearly constant leg stiffness during running [33–35]. Furthermore, we report an inverse relationship between leg stiffness and running speed, despite a positive association between prosthetic stiffness and running speed (figure 3). This occurs because leg stiffness only increases  $0.21 \text{ kN m}^{-1}$  with each integer increase in prosthetic stiffness, whereas it decreases  $0.58 \text{ kN m}^{-1}$  with every  $1 \text{ m s}^{-1}$  increase in running speed. For example, the  $3.2 \text{ kN m}^{-1}$  average increase in prosthetic stiffness from 3 to  $7 \text{ m s}^{-1}$ , coupled with the influence of faster running speed yields a  $1.65 \text{ kN m}^{-1}$  reduction in leg stiffness (figure 3).

The leg joint mechanics that govern overall leg spring behaviour may differ between athletes with and without transtibial amputations. A previous study indicated that the affected leg knee joints of athletes with unilateral transtibial amputations do not act like sagittal plane torsional springs during running [12], which is dissimilar to that of non-amputees [36,37] whose knee joint mechanics greatly influence leg stiffness [38]. We confirmed that at each speed, the overall leg mechanics of athletes with bilateral transtibial amputations follow the main assumptions of the spring–mass model [1–6], where the vertical GRFs and displacement of the runner's CoM gradually increase then decrease with both maximums occurring at approximately 50% of the stance phase (figure 6). Future analyses of residual limb joint mechanics (hip, knee, residual limb/socket interface, etc.) are necessary to determine if leg joints and the limb–socket interface of athletes with bilateral transtibial amputations perform like springs (linear and torsional springs) during running and how they contribute to the spring-like behaviour of the overall leg.

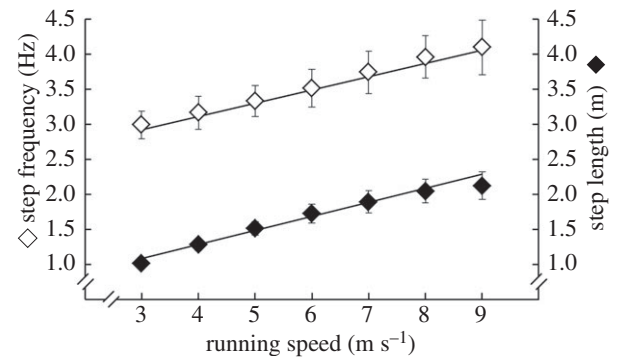
We rejected our second hypothesis that prosthetic height would be independent of the biomechanical variables that comprise the spring–mass model and govern running speed. Notably, increased prosthetic height was associated with longer contact lengths, ground contact times and step lengths. Intuitively, athletes with longer legs take longer steps during running, yet non-amputees exhibit a very weak association between leg length and step length during running [39]. Thus, leg length may have a stronger influence on step length in athletes with bilateral transtibial amputations compared with non-amputees.





**Figure 6.** Representative vertical GRF traces (left axis), and CoM vertical displacements ( $\Delta Y$ ; right axis) as a function of time for a participant using Össur Cheetah Xtend prostheses at (a) -1 prosthetic stiffness category, (b) recommended prosthetic stiffness category and (c) +1 prosthetic stiffness category. Light grey lines represent running at 3 m s<sup>-1</sup>, medium grey lines represent running at 6 m s<sup>-1</sup> and black lines represent running at 9 m s<sup>-1</sup>. On average, peak and stance average vertical GRFs increased with speed ( $v$ ) ( $p < 0.001$ ). Linear regressions for all participant and prosthetic combinations that achieved speeds 3 through 9 m s<sup>-1</sup> were peak vertical GRF =  $0.115 v + 2.439$ ,  $R^2 = 0.48$ ,  $p < 0.001$ ; stance average GRF =  $0.047 v + 1.513$ ,  $R^2 = 0.38$ ,  $p < 0.001$ . However, some participant and prosthetic combinations (e.g. this figure) increased running speed despite decreasing vertical GRFs from 6 to 9 m s<sup>-1</sup>.

Regarding distance running performance, the metabolic cost of running for athletes with bilateral transtibial amputations is independent of prosthetic height, but is reduced with lower leg stiffness, step frequency and peak braking



**Figure 7.** The average ( $\pm$  s.e.) elicited step frequency (StF) and step length (StL) at each running speed ( $v$ ) across all prosthetic configurations. Linear regression equations follow as: StF =  $0.20 v + 2.35$ ,  $R^2 = 0.67$ ,  $p < 0.001$ ; StL =  $0.20 v + 0.49$ ,  $R^2 = 0.88$ ,  $p < 0.001$ .

horizontal GRFs [11]. In this study, increased prosthetic height was independent of leg stiffness, but it did reduce step frequency. Perhaps taller RSPs increase lower-limb mass and/or inertia, counteracting the potentially beneficial effects of running with slower step frequencies [40,41]. Moreover, many surmise that increased prosthetic height augments sprinting performance for athletes with bilateral transtibial amputations [19,20]. Overall sprinting performance is beyond the scope of this study. Nonetheless, increased prosthetic height resulted in diminished stance average vertical GRFs and prolonged ground contact durations, both of which suggest slower running speeds [14,15]. Assuming that leg segment geometry is unchanged, perhaps the vertical GRF impairment with taller RSPs is related to worse hip and knee joint effective mechanical advantages [15,42]. Alternatively, achieving the same running speed with lower stance average vertical GRFs may be beneficial for sprinting performance. Thus, future research is warranted to better understand leg segment geometry and the effective mechanical advantage of the leg joints with changes in prosthetic height.

The influence of prosthetic stiffness on biomechanics was mitigated at faster running speeds (figures 4 and 5), leading us to accept our third hypothesis. The stiffness of a system encompassing two in-series springs is primarily influenced by the softer spring (equation (2.4)). Because the residual limb stiffness of athletes with bilateral transtibial amputations is roughly twice that of the RSP at 3 m s<sup>-1</sup>, and approximately equal to that of the RSP at 7 m s<sup>-1</sup>, prosthetic stiffness has a greater influence on running biomechanics at slower speeds than at faster speeds (figure 3).

It has yet to be established whether athletes with and without bilateral transtibial amputations take similar step lengths at matched running speeds. In this study, from 3 to 5 m s<sup>-1</sup>, participants exhibited greater overall leg stiffness [5], decreased contact lengths and durations, and lower stance average vertical GRFs, leading to 7–11% shorter steps compared with non-amputees [39,43]. From 5 to 8 m s<sup>-1</sup>, the leg stiffness values of athletes with and without transtibial amputations converge as running speed increases [2,4,44] (figure 3), leading to similar leg stiffness, contact length/duration and step length values between groups. At speeds faster than 8 m s<sup>-1</sup>, step length comparisons made in previous studies between one athlete with bilateral transtibial amputations and non-amputees are conflicting. Initially, Brüggemann *et al.* [18] reported no difference in step length between an athlete with bilateral

transtibial amputations and performance matched non-amputees at approximately  $9 \text{ m s}^{-1}$  during over ground running (2.26 m for the athlete with bilateral transtibial amputations). Alternatively, Weyand *et al.* [16] reported that the same athlete (during a subsequent test) took shorter steps at  $10 \text{ m s}^{-1}$  versus a different non-amputee control group during treadmill running (2.03 versus 2.37 m, respectively). The athletes in this study took step lengths that averaged 2.24 m at  $9 \text{ m s}^{-1}$ , consistent with Brüggemann *et al.*'s report [18] (figure 7). Yet, different athletes and testing procedures may confound inter-study comparisons [16,18].

Regardless, because prosthetic stiffness and height affect step length for athletes with bilateral transtibial amputations, there is likely a prosthetic configuration that yields similar step lengths for athletes with and without amputations at each speed. Furthermore, during some sets of running trials, participants increased running speed beyond  $7 \text{ m s}^{-1}$  by using shorter and more rapid steps. This adaptation may explain the shorter step lengths measured by Weyand *et al.* [16] at  $10 \text{ m s}^{-1}$  versus that of Brüggemann *et al.* [18] at  $9 \text{ m s}^{-1}$ . Altogether, athletes with bilateral transtibial amputations generally increase both step length and step frequency to achieve faster running speeds (figure 7), but they can also increase running speed by decreasing step length and rapidly increasing step frequency.

We excluded the analysis of prosthetic model on running biomechanics because models, like running shoe models, are continually changing. Still, many differences exist between prosthetic models (figure 2), including but not limited to geometry (figure 2), stiffness [21], socket attachment (figure 2), hysteresis [21], mass [11,22] and moment of inertia [45]. Thus, a detailed analysis and simulation of RSP design on the running biomechanics of athletes with bilateral transtibial amputations may be insightful to further optimize RSPs.

A limitation of this study includes the use of different prosthetic sockets with C- versus J-shaped RSPs. This may have led to altered residual limb movement within the socket, potentially leading to altered running biomechanics. Participant fatigue may have limited our protocol. To mitigate fatigue, we limited the performed sets of running trials for each respective session to 0 (rest), 1, 2 or 3 sets, depending

on athlete feedback. Owing to our efforts in minimizing fatigue plus the randomization of prosthetic configuration, we believe that participant fatigue had a negligible influence on the RSP configuration results. Yet, potential fatigue may have influenced the running speed results because of the systematic trial order. Furthermore, our relatively small sample size may have led us to falsely accept null hypotheses.

## 5. Conclusion

Athletes with bilateral transtibial amputations change their running biomechanics when using RSPs that differ in stiffness, height and while running at different speeds. Namely, the use of stiffer RSPs increased leg stiffness, step frequency, peak and stance average vertical GRF production, and decreased ground contact time. The use of taller RSPs increased step length. Running speed was inversely associated with leg stiffness. Moreover, faster running speeds mitigate the effect of prosthetic stiffness, but not height, on running biomechanics. Therefore, prosthetic stiffness, but not height, likely has a greater influence on distance running performance than on sprinting performance for athletes with bilateral transtibial amputations.

**Data accessibility.** Running mechanics data: <https://figshare.com/s/5ab1b28c7eb9b5476f9a> [46].

**Authors' contributions.** A.M.G. contributed to the concept and design of the study, analysis and interpretation of data, drafting and revising of the manuscript, and approved the version of the manuscript to be published. P.T. and O.N.B. contributed to the acquisition of data, analysis and interpretation of data, drafting and revising of the manuscript, and approved the version of the manuscript to be published. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of the work are appropriately investigated and resolved.

**Competing interests.** We declare we have no competing interests.

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